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FINAL REPORT

DETERMINATION OF PERSONAL EXPOSURES TO ENVIRONMENTAL TOBACCO SMOKE IN BRITISH NON-SMOKERS

HAZLETON UK

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CONFIDENTIAL

FINAL REPORT

DETERMINATION OF PERSONAL EXPOSURES TO ENVIRONMENTAL TOBACCO SMOKE IN BRITISH NON-SMOKERS

Report for:
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Report No: 12/64-1012

Date: June 1993

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AUTHENTICATION

REPORT NO 12/64-1012

I, the undersigned, hereby declare that the work described was performed under my supervision, in accordance with the Hazleton Manual of Standard Operating Procedures, and that the report provides a true and accurate record of the results obtained.

K Phillips

K Phillips, CChem, FRSC
Study Director
Biopharmaceutical Analysis

Date: 15 June 1993

I, the undersigned, hereby declare that I have reviewed this report in conjunction with the Study Director and that the interpretation and presentation of the data in the report are consistent with the results obtained.

T. H. Houseman

Dr T H Houseman, CChem, FRSC
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Date: 15 June 1993

The following scientific personnel were involved in the study under the overall supervision of the Study Director.

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QUALITY ASSURANCE RECORD HUK Report no: 12/64-1012

The study described in this report was subject to audit/inspection by the independent HUK Quality Assurance Unit for the aspects and at the intervals specified below. The findings of each audit were reported to the Study Director and HUK management as prescribed by QA Standard Operating Procedures.

Phase of study audited	Date of audit	Date of report
Protocol review	15 October 1992	15 October 1992
Study Inspection	13 October 1992	15 October 1992
Study Inspection	15 October 1992	15 October 1992
Study Inspection	27 October 1992	6 November 1992

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KEY TO ABBREVIATIONS USED IN FIGURES AND TABLES

Sub	- Subject
No	- Number
PAS	- Particles from all Sources
UVPM	- ETS Particles as estimated by Ultra-violet Spectroscopy
FPM	- ETS Particles as estimated by Fluorescence Spectroscopy
SPM	- ETS Particles as estimated from Solanesol determination
3-eth	- 3-ethenylpyridine
Pre Cot	- Salivary Cotinine sampled prior to monitoring period
Post Cot	- Salivary Cotinine sampled at end of monitoring period
ETS	- Environmental Tobacco Smoke
ND	- Not Detected
NA	- Not Analysed
Sp'se	- Spouse
P'ner	- Spouse or Partner
N	- No
Y	- Yes
$\mu g/m^3$	- Micrograms per Cubic Meter
ng/mL	- Nanograms per Millilitre
M	- Male
F	- Female
Mod	- Moderate
V	- Very

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1. SUMMARY

During the Autumn of 1992, British volunteers were recruited to wear personal monitors for 24 hours in order to assess ETS exposure. All volunteers were recruited on the basis that they lived or worked in Leeds or Harrogate, that they were non-smokers and that they were taking part in an Air Quality survey. Out of 327 subjects, 72 were excluded for various reasons, including 53 suspected of smoking and 255 valid monitoring sessions were completed.

Measurements were made of exposure to particles form all sources, particles associated with ETS, and nicotine. Subjects supplied saliva samples for cotinine analysis at the start and end of the monitoring period and a questionnaire about smoke exposure and general lifestyle was completed.

Questionnaire data showed that approximately 80% of subjects assessed their ETS exposure as either 'none' or 'low'. Direct measurements of exposure by personal monitoring support this and also show that the mean overall levels for ETS particles was 12 $\mu g/m^3$, for nicotine 1.7 $\mu g/m^3$ and for the pre and post cotinine 1.4 ng/mL.

ETS particles were found to be only a relatively small percent (7%) of particles from all sources.

Subjective assessments indicate overall that the ranking of sources of exposure is LEISURE > WORK > HOME > TRAVEL. Over 40% of subjects assessed leisure as their principal source of exposure. Travel was perceived as only a minor contribution to total ETS exposure. In contrast, data derived from 24 hour measurements by personal monitoring indicate the ranking is HOME > LEISURE > WORK > TRAVEL. Both subjective and directly measured estimates indicate that travel was a minor source of exposure.

Results indicate that for the group as a whole, non-smokers with a spouse/partner who smokes are exposed to more ETS than non-smokers with a spouse/partner who is a non-smoker. However, there are marked variations among individual subjects. For

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example, 46% of non-smokers with a smoking spouse/partner assessed their ETS exposure as 'none' or 'low'. Direct measurements supported these assessments. Also, approximately 30% of the subjects with a smoking spouse/partner assessed work or leisure as their principal source of exposure.

Overall the Direct Measurements of SPM, nicotine and salivary cotinine levels were consistent with subjective assessments of exposure obtained by questionnaire. However, there was considerable variation in the way individual subjects perceived similar ETS levels. This demonstrates that an individual's exposure to ETS cannot be reliably assessed by the use of a simple questionnaire but there should be supplementary information obtained from direct measurements.

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2. INTRODUCTION

Two main approaches have been used in the past to assess whether there is any risk associated with exposure to ETS. One is based on epidemiology and the other on the quantities of smoke constituents to which non-smokers are exposed.

A criticism of published epidemiological studies of ETS exposure is that they failed to include direct measurements of exposure levels. Spousal smoking has frequently been used as an index of ETS exposure in these studies but the validity of this approach is open to question. Therefore, it is important to determine whether reported spousal smoking correlates well with directly measured exposure. It is also important to assess how well directly measured ETS exposure can be predicted by questionnaire, or by measurements of salivary cotinine, because these methods are also used as an alternative to direct measurements of exposure.

Most of the information about the exposure of non-smokers to ETS is based on measurements of ETS levels in locations such as homes, offices, and restaurants together with assumptions about the time people are thought to spend in these locations. There have been several such studies conducted, particularly in the USA, but none has provided sufficient information to characterise properly the range of ETS exposure experienced by non-smokers.

There have, until recently, been few attempts to measure directly the exposure of people as they go about their normal lives, moving from location to location, even though this approach should provide more realistic results than those calculated from ETS levels in locations. Although the use of 'personal monitoring' has been common practice in the industrial hygiene field for several years, it is only recently that the analytical methodology has been refined sufficiently to allow ETS measurements to be carried out by this approach. A few ETS exposure studies involving personal monitoring have now been completed or are underway. Nevertheless, further information is required with which to address some of the important issues relating to ETS.

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Although levels of both nicotine and ETS particles have been determined in several studies of locations, personal monitoring studies have tended to measure nicotine but not particles. In view of the limitations of nicotine as a marker for ETS and the importance often attached to particles, there clearly is a need for personal monitoring studies in which nicotine and ETS particles are measured simultaneously. This is possible now that the UVPM (ie ETS particulate matter measured by ultra-violet light), FPM (ie ETS particulate matter measured by fluorescence) and solanesol methods are available for estimating the ETS contribution to total particles.

There is an increasing trend for smoking bans to be introduced in the workplace and in various public leisure and travel situations. There is also increasing debate about smoking at home, especially in the presence of children. Therefore it would be helpful to obtain further information on the extent of exposure at home, work, leisure and travel in order to assess how each contributes to overall ETS exposure. This type of objective data would allow decisions about ETS exposure to be taken on a more informed basis.

The specific objectives of this project were as follows:

1. To determine the range, mean and median levels of 24-hour exposure to nicotine and to ETS particles for non-smoking British volunteers.

2. To assess the contributions to total ETS exposure from the home, the workplace, leisure and travel.

3. To assess whether non-smokers who are married to smokers have significantly higher exposures to ETS than non-smokers married to non-smokers.

4. To compare questionnaires, direct measurements and salivary cotinine levels as methods of assessing exposure to ETS.

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To meet these objectives, 327 non-smokers were randomly selected for the study. Each subject's exposure to ETS was determined over a 24 hour period by a personal

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monitoring method. Measurements were made of nicotine and particles from all sources. The contribution of ETS to the total particles collected was assessed by UV, fluorescence and solanesol measurements.

Although not a part of the agreed objectives, 3-ethenylpyridine was also measured as it was collected and analysed simultaneously with nicotine.

Subjects completed a time-activity diary during the monitoring period which included a record of whether tobacco smoke was present. A post-sampling questionnaire was completed on perceived exposure levels, times spent in various locations, smoking by spouse or partner etc. The subjects were not aware that the study was related to ETS as they had been told that it was an air quality study.

Cotinine levels were measured in saliva samples taken at the beginning and end of the monitoring period.

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3. STUDY DESIGN

3.1 Pilot study

Prior to the start of the main study, a pilot study was conducted using ten subjects. The purpose of the trial was to evaluate and assess all aspects of the study design. This included evaluation of the delivery and collection of monitors, completion of diaries and questionnaires, and analysis of samples. This pilot study was successful and resulted in only minor modifications being incorporated into the main study.

3.2 Main study

3.2.1 Subject selection

280 non-smokers were randomly selected from an existing data base of 15,000 volunteers held at Besselaar Clinic, Leeds, England (See Appendix 2). The subjects were either working or resident in the Harrogate or Leeds postal districts for at least three months prior to and during the study period. Their ages ranged between 21 and 61 years and selection was reasonably representative in terms of age and sex distribution (see Appendix 6.8). As subjects dropped out, did not keep their appointments, pumps failed, reported non-smokers were identified as smokers, further subjects were recruited bringing the total number of subjects included to 327. There were approximately 70 different occupations including housewives, policemen, musicians, solicitors, mechanics, civil servants, dentists, cooks etc. (See Appendix 6.7).

3.2.2 Delivery and collection of monitors

All locations were selected by Besselaar Clinic's staff in advance (see Appendix 2). Regular contact with the clinic and Hazleton UK was maintained by car phone during delivery and collection.

Deliveries were in the mornings in Leeds and the afternoons in Harrogate. Generally collection was after 24 hours but in all cases was between 23 and 25 hours following delivery.

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3.2.3 Start of the monitoring period

On delivery, the use of the pump and wearing of the monitor was explained. A diary was provided for completion during the monitoring period. The pump was switched on by the investigator and a saliva sample obtained (pre sample) by the subject chewing on a dental swab for a measured 1.5 minutes (Appendix 3).

3.2.4 End of the monitoring period

On collection, the pump was switched off by the investigator. A post saliva sample was taken in an identical way to the pre-sample. Diaries were checked and collected and the questionnaires completed by the investigator who asked the questions and recorded the answers.

3.2.5 Collection and analysis of airborne nicotine, 3-ethenylpyridine and particulates

The collection of these analytes was achieved by the subjects wearing the compact monitor and pumping system (See Appendix 3, Figure 2) for the duration of the monitoring period. The first filter of the two in series collected the particles from all sources (PAS) and the second, which was acid-treated, trapped the nicotine vapour and 3-ethenylpyridine.

At the end of the monitoring period the filter holders were returned to Hazleton UK, Harrogate, England for analysis. The filters were weighed to determine PAS and extracted with methanol. The extracts were analysed for nicotine, 3-ethenylpyridine, UVPM (particles measured by UV light), FPM (particles measured by fluorescence) and solanesol (SPM).

3.3 Methods of analysis (in brief)

Summaries of the methods of analysis are presented here. Full details can be found in Appendix 4 together with appropriate calibration data and typical chromatograms.

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3.3.1 UVPM, FPM and SPM

The particles from all sources collected on the Millipore Teflon filters were extracted with methanol. UV and fluorescence measurements were made on the extract using an HPLC method (without the use of a column) and compared to calibrations made using surrogate standards for ETS particulates (Scopoletin for FPM and Tetrahydroxybenzophenone (THBP) for UVPM). These surrogate standards were themselves calibrated by the sponsor against ETS particles generated in a Model Room.

The solanesol content of the extract was determined using an HPLC method with UV detection. Solanesol based ETS particles (SPM) were determined using a factor calculated from the solanesol content of ETS particles generated in a Model Room. This factor was supplied by the sponsor.

3.3.2 Nicotine and 3-ethenylpyridine

Any nicotine and 3-ethenylpyridine collected on the front filter was extracted as above. An aliquot of this extract was basified with sodium hydroxide solution and the nicotine and 3-ethenylpyridine extracted using di-isopropylether containing triethylamine and an internal standard.

Nicotine and 3-ethenylpyridine collected on the second filter was extracted following basification as above.

The nicotine and 3-ethenylpyridine were determined using a GC method with nitrogen selective detection.

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3.3.3 Cotinine

Saliva samples were centrifuged in their salivettes. Internal standard (N-ethylnorcotinine) was added to 0.5 mL of the saliva which was then extracted using dichloromethane under basic conditions. The cotinine was determined by GC using a mass selective detector.

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4. RESULTS AND DISCUSSION

4.1 Excluded subjects

All results for some subjects were excluded from the study for the following reasons:

REASON	NUMBER EXCLUDED
Subjects did not keep their appointment	5
The pump did not run for the full 24 hours	6
One of the Hazleton analysts was a smoker*	14
Smoke was deliberately blown into the monitor	6
Subjects admitted smoking during the monitoring period	7
Subjects had salivary cotinine levels above threshold	34

* On one occasion an analyst who claimed to smoke occasionally was involved with the testing of a batch of personal monitors. This was in breach of the protocol and the results from 14 subjects were invalidated.

Thus from 327 subjects selected, 72 were excluded and 255 sets of usable results were obtained.

Seven subjects were rejected for smoking during the monitoring period (questionnaire) and 34 subjects were rejected with cotinine levels $\geq$ 25 ng/mL. For the purposes of this study they were assumed to be smokers but some could conceivably be users of other forms of nicotine administration (eg gum, patches). The questionnaire did not address the use of other forms of nicotine administration. However, none of the subjects volunteered any such information, although questioned in detail about their smoking habits.

The 34 subjects who were excluded as a result of high cotinine levels were contacted by phone and letter after completion of the study. Responses were received from 17 of these 34 subjects. Fifteen of these confirmed that they had not used any form of nicotine administration system and these subjects must therefore be regarded as smokers.

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In a review of salivary cotinine levels, Etzel (1990) reported that non-smokers usually have levels below 5 ng/mL, but heavy exposure can result in levels around 10 ng/mL. The 25 ng/mL criterion used in this study was chosen to avoid the possibility that heavily exposed non-smokers might be incorrectly rejected.

There is some debate as to what salivary cotinine cut-off level should be used to detect smokers or nicotine users. From the 327 subjects tested in this study, the number that would be rejected at different cut-off levels of salivary cotinine is as follows:

Cut-off level	Number rejected
10 ng/mL (Etzel, 1990)	47
15 ng/mL (McNeill, 1987)	41
25 ng/mL	41
30 ng/mL (Lee, 1987)	37
50 ng/mL	34
100 ng/mL (EPA criterion for regular smoker see Section 4.2)	23

These results show that the salivary cotinine cut-off point used to distinguish between smokers and non-smokers on this study is not very critical, especially in the range 15 to 30 ng/mL.

Some of the subjects were found to have very high cotinine levels and those with levels ≥ 100 ng/mL are listed below to indicate the number of subjects involved and the range of levels in which they were distributed. Sixteen subjects had pre or post cotinine levels > 300 ng/mL, the highest being > 700 ng/mL.

Excluded subjects

Number of subjects	Cotinine range (ng/mL)
2	100 - 150
3	150 - 200
1	200 - 300
7	300 - 400
7	400 - 500
2	500 - 800

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4.2 Misclassification

Misclassification occurs in ETS studies when smokers report themselves as non-smokers, or vice-versa. This has important consequences when attempts are made to assess whether there is any risk associated with ETS exposure (Lee 1988).

It was not an objective of this study to assess misclassification and it was not anticipated that it would occur to a substantial level especially as the subjects were members of a documented group held on a data base used for medical trials.

All subjects were recruited on the basis that they were non-smokers. Also, a recruitment questionnaire was completed for each subject confirming this non-smoker status.

In view of these recruitment criteria, it was surprising to find that 41 subjects had to be excluded for smoking, or possibly other nicotine usage. Furthermore, 12 other subjects admitted smoking following recruitment as non-smokers. These 12 subjects were not excluded from the study because they did not smoke near to the time of their monitoring session (Questionnaire) and they were not identified as smokers by their salivary cotinine measurements.

The median salivary cotinine level for self reported smokers (or nicotine users) in the UK was reported by LEE (1987) to be 319 ng/mL for men and 311 ng/mL for women. The EPA has defined regular smokers as those with more than 30% of the average cotinine level found for smokers.

Therefore some subjects, especially those with cotinine above 100 ng/mL, were likely to be regular smokers and had, nevertheless, incorrectly described themselves as non-smokers. Others may have been occasional smokers and yet genuinely regard themselves as non-smokers. This indicates that careful questioning is required to determine if a person, or a person's spouse, is a smoker.

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Because 12 subjects admitted to recent occasional smoking (Questionnaire) and yet were not identified as smokers by salivary cotinine measurements, it seems that such body fluid measurements could well underestimate misclassification rates in other studies.

It is possible that other subjects had smoked occasionally since recruitment, did not admit to doing so and were not detected by salivary cotinine level. A combination of a well-designed questionnaire and salivary or urinary cotinine measurements is clearly required to detect most cases of misclassification but even then some smokers may not be detected.

In summary:
Seven subjects admitted smoking during the monitoring period.
Twelve subjects admitted smoking since recruitment but not at the time of the monitoring period.
These 19 subjects were clearly misclassified as non-smokers.

Thirty-four subjects were suspected of smoking based on their salivary cotinine levels, 15 of these 34 subjects contacted after the study confirmed that they had not used any form of nicotine administration system such as gum or a patch.

These 15 subjects are almost certainly smokers. Two subjects contacted after the study reported that they had used a nicotine administration system (patches in both cases). The remaining 17 out of the 34 did not respond

The level of misclassification of smokers as non-smokers found in this study is at least 10% (19 admitted smoking and 15 identified as smokers out of 327 subjects) but is probably much closer to 16% (53 out of 327 subjects). This is consistent with levels of misclassification found in other studies.

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4.3 Relevance of 24 hour sampling

In order to assess how representative the 24-hour sampling period was, subjects were asked to make a comparison of their ETS exposure during the sampling period with their average exposure over the last six months. The results were as follows:

Subjective assessment	Number	% of total
Much less than normal	25	9.8
Less than normal	91	35.7
Fairly typical of average exposure	131	51.4
More than normal	7	2.7
Much more than normal	1	0.4

Over 50% of subjects assessed their exposure in the monitoring period was typical of their average exposure. However, on balance, the subjects assessed their exposure to be somewhat less than normal.

For all subjects who claimed they were exposed to ETS during the monitoring period (156) subjective assessments were made of the relative contributions of home, work, leisure and travel to total ETS exposure. The mean values for these results in the monitoring period and for the previous six months are compared below.

	% Contribution to overall ETS exposure	
	Monitoring period	Last six months
Home	27.8	19.8
Work	31.5	29.4
Leisure	35.1	46.3
Travel	5.7	4.7

[It could be argued that the comparison of results for home and leisure indicate that wearing the monitor caused the subjects to spend more time, relative to the last six months, at home instead of at leisure. On the other hand, it is probable that subjects would spend more time at home in October to December (study period) than they would throughout the previous six summer months.]

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Objective evidence that the monitoring period was not abnormal relative to the previous day is that the mean results for the pre-monitoring salivary cotinine levels are in close agreement with the post-monitoring levels.

Taken together the subjective and objective results indicate that the monitoring period was not abnormal compared with recent exposure. This suggests that wearing the monitor did not seriously interfere with normal lifestyle.

4.4 Weather conditions during the study

It was decided not to conduct the study during the summer months when ETS exposure was likely to be at a minimum. Similarly, it was decided not to conduct the study during peak winter conditions when the exposure to ETS would probably be at its highest and the practical difficulties of conducting the study at their greatest. Therefore October to early December was chosen as a compromise time period.

Accurate information on the prevailing weather conditions between 4 October 1992 and 12 December 1992 was supplied by The Meterological Office, Leeds Weather Centre, Leeds, England. Measurements were observed daily for the Harrogate and Leeds districts with any significant differences being noted. The official data are in Appendix 6.6.

A summary based on weekly minimum, maximum and mean values (where applicable) of temperature, relative humidity, rainfall hours of sunshine and wind speed is presented in Figure 1.

It can be seen that there was a wide variation in weather conditions throughout the study. The minimum temperature recorded was -3.2°C and the maximum 16.9°C, both in early November. The minimum %RH was 55.0 and the maximum 96.0. The maximum daily rainfall was 10.4 mm. The maximum recorded sunshine was 7.5 hours during week 2 of the 10 week study. Wind speed varied from a low of 4 knots to a high of 26 knots. The highest gust recorded was 61 knots during

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week 4. Hail was observed on 10, 19 and 26 November 1992. Sleet was also observed on 25, 27 October and 12 November 1992.

In Figure 2 the mean weekly SPM and PAS values for the subjects monitored are listed together with the mean values of temperature, %RH and Hours of sunshine for the same periods. It can be seen that there is no obvious relationship between mean weather conditions and measured ETS exposure.

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FIGURE 1

WEATHER CONDITIONS (MEAN WEEKLY VALUES)

Date	Week number	Subject number	Temperature (°C)			Rainfall (mm)		% RH			Hours sunshine			Wind speed (kt)	
			Min	Max	Mean	Min	Max	Min	Max	Mean	Min	Max	Mean	Min	Max
6-12 Oct	1	1-37	7.3	14.2	9.9	0.0	5.0	61.0	76.0	67.6	0.0	5.0	1.5	6	11
13-19 Oct	2	38-68	-0.9	11.9	7.0	0.0	1.9	55.0	74.0	64.7	0.0	7.5	4.7	4	17
20-26 Oct	3	69-106	0.3	10.5	5.7	0.0	9.7	61.0	94.0	77.0	0.0	6.3	2.6	5	13
27-2 Nov	4	107-139	-0.2	12.1	6.9	0.0	4.5	60.0	88.0	71.7	0.0	7.0	4.4	7	26
3-9 Nov	5	140-179	-0.6	16.9	10.0	0.0	8.3	65.0	89.0	66.6	0.0	5.0	1.7	4	14
10-16 Nov	6	178-219	-3.2	8.8	4.5	0.0	5.9	62.0	91.0	77.9	0.0	7.3	2.7	6	18
17-23 Nov	7	220-251	1.3	15.0	7.8	0.0	10.4	54.0	96.0	76.4	0.0	6.7	2.8	4	20
24-30 Nov	8	252-289	-0.2	13.0	7.3	0.0	4.6	72.0	94.0	79.1	0.0	5.0	2.3	5	15
1-7 Dec	9	290-305	1.6	12.8	5.7	0.0	7.6	77.0	89.0	82.7	0.0	2.5	1.3	6	14
8-12 Dec	10	306-327	1.6	9.9	5.9	0.0	7.1	75.0	94.0	84.8	0.0	2.4	0.8	5	9

% RH = % Relative Humidity Wind speed kt = knots

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FIGURE 2

MEAN WEEKLY VALUES OF SPM, PAS, TEMPERATURE, % RH AND HOURS OF SUNSHINE

Week number	SPM ($\mu g/m^3$) Mean	PAS ($\mu g/m^3$) Mean	Temperature (°C) Mean	% RH Mean	Hours of Sunshine Mean	Max wind speed (Kt)
1	10	177	9.9	67.6	1.5	11
2	9	157	7.0	64.7	4.7	17
3	13	220	5.7	77.0	2.6	13
4	18	187	6.9	71.7	4.4	26
5	6	161	10.0	66.6	1.7	14
6	14	196	4.5	77.9	2.7	18
7	4	141	7.8	76.4	2.8	20
8	21	180	7.3	79.1	2.3	15
9	8	159	5.7	82.7	1.3	14
10	28	214	5.9	84.8	0.8	9

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4.5 The analytical methods: General observations

Full details of the methods used are provided in Appendix 4.

4.5.1 Particles from all sources

It would have been preferable on this study to measure Respirable Suspended Particles (RSP) which are particles below a certain diameter (5 to 10 μ depending on definition). However, it would not have been possible to achieve the necessary size discrimination at the low sampling flow rate used in this study. At higher flow rates, an impaction device or a cyclone could be used to achieve the required size discrimination but the battery-operated sampling pump would then not have operated for 24 hours.

If particles are collected with no size selection at all then the collected material is referred to as Total Suspended Particles (TSP). Since the larger particles in TSP cannot be inhaled, less importance is attached to this measure.

The particles collected with the personal monitor used in this study are neither RSP nor TSP. Calculations (Dr I Colbeck, Essex University) based on the sampling flow rate and the entrance plate dimensions suggest that particles of respirable size ($< 10 \mu$ diameter), including ETS, would be collected very efficiently by the personal monitor and this has been confirmed experimentally by the sponsor. These calculations also indicate that the collection efficiency should fall to zero for particles of around 50 μ diameter or more.

To avoid any confusion with RSP or TSP, the term PAS is used in this report to refer to the Particles from All Sources as collected by the personal monitor.

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

It is to be expected that the measurement of PAS will tend to give results which are a little higher than RSP and lower than TSP.

4.5.2 ETS Particles

ETS particle values reported in this Results and Discussion section are based on estimation by the solanesol method and are referred to as SPM (See Appendix 4). This method proved to be a more selective measure of ETS contribution than UVPM or FPM. Results for UVPM and FPM are given in Appendix 6.1.

As might be expected, UVPM measurements can considerably overestimate the ETS particle contribution to PAS because many particles not associated with ETS also absorb UV light. FPM measurements are less prone to interference than UVPM but there is still some fluorescence from particles that are not associated with ETS. Solanesol measurements are almost totally free from interference.

Clearly, the situation where the greatest over estimation of ETS by UVPM and FPM measurements is to be expected when a PAS level is high but the ETS contribution is very low.

The selectivity of the three methods is reflected in the individual, the mean and the median results obtained in the study (see Figure 4).

Ogden et al (1990) have compared the relative merits of the UVPM, FPM and solanesol-based methods for estimating ETS particle contributions to RSP. They also concluded that the UVPM method can considerably overestimate ETS particles, and that the FPM method is less prone to interference but is not as selective as solanesol-based methods.

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

4.5.3 Salivary cotinine

Salivary cotinine measurements were made by a GCMS method. The detection limit was 0.5 ng/mL, which is higher than the best detection limit of 0.1 ng/mL reported for GC with nitrogen specific detection (NPD). However, experiments with GC-NPD showed that it was not possible to be certain of cotinine peak identification at low levels in saliva samples. This is due to the variable composition of the saliva matrix and the presence of nitrogen containing compounds with similar retention times to cotinine.

4.5.4 Detection limits

Detection limits for the analytical methods used were found to be as follows:

PAS	20 $\mu g/m^3$
UVPM	8 $\mu g/m^3$
FPM	4 $\mu g/m^3$
SPM	4 $\mu g/m^3$
Nicotine	0.1 $\mu g/m^3$
3-Ethenylpyridine	0.1 $\mu g/m^3$
Salivary cotinine	0.5 ng/mL

Reference to the tables of analytical results in Appendix 6.1 shows that in many cases levels of components are below the limit of detection for the method used. This raises the question of how to deal with these results in the calculation of means, medians etc in the data analyses. If a value of zero is applied when results are below the limit of detection then this would underestimate the true level of exposure for some subjects. Conversely, if the value of the detection limit itself was applied in such cases then the exposure of some subjects would be overestimated. As a reasonable compromise, a value which is one half of the detection limit has been used for the data analyses carried out in this report. The same compromise has been used in other studies of this type.

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

4.5.5 Expression of mean results

When reporting results, both the mean and the median values of data sets are quoted together with the range of the values. In this type of study where the results are far from being normally distributed the median is a more appropriate measure than the mean because one or two exceptionally high values can have a disproportionately large effect on the mean when most of the other values are relatively low. Both the mean and the median will be referred to as appropriate, but generally most importance should be attached to median results.

4.6 Consistency of results with those from other studies

4.6.1 PAS

Results for PAS are reasonably consistent with results for RSP in other studies. However, the comparisons have to be made with the results from measurements in locations (see below) because there are insufficient data from personal monitoring studies.

Ogden (1990) has reported on the use of solanesol measurements for estimating the ETS contribution to RSP levels. However, only a limited number of results were reported which did not involve personal monitoring and cannot usefully be compared with the data from this study.

There have, however, been several recent studies in which UVPM has been measured and these have been summarised by Guerin et al (1992) as follows:

	Mean particle levels $\mu g/m^3$	
	UVPM	RSP
42 restaurants	26*	62*
10 trains, smoking compartments	60	216
10 trains, non-smoking compartments	33	186
5 betting shops	164	333
125 offices	27*	126*
82 restaurants	36*	126*

* geometric mean

Corresponding results for this study are consistent with the above results:

This study	31	179 (PAS)

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

4.6.2 Nicotine

Nicotine levels found in this study are in good agreement with other recent studies. The most similar study to the current one is that reported by Proctor et al (1991) who measured the nicotine exposure of 52 women in Birmingham, England by a personal monitoring technique:

	Nicotine $\mu g/m^3$			
	Maximum	Minimum	Mean	Median
This study	26	0.05	1.7	0.5
Proctor et al	45	0	2.3	0

The results from these two studies for nicotine are in close agreement.

4.6.3 Cotinine

Salivary cotinine levels found in this study are also in close agreement with those reported by Proctor et al in the same publication:

		Salivary cotinine ng/mL			
		Maximum	Minimum	Mean	Median
This study	Pre-sample	14	0.25	1.4	0.7
	Post-sample	12	0.25	1.4	0.6
Proctor et al	Pre-sample	15	0.3	1.8	1.2
	Post-sample	9	0	1.5	1.1

The exposure levels measured in this study are in good agreement with results from other studies. This would indicate that the personal monitoring technique and analytical methods used in this study are valid.

4.7 Cigarette equivalents

Some authors have used the concept of 'cigarette equivalents' in an attempt to put ETS exposure levels into perspective. This approach has the advantage of providing the layman with a comprehensible measure of the quantity of ETS inhaled as a result of ETS exposure. However, the inhalation of ETS is different

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in several important ways from the inhalation of mainstream cigarette smoke during active smoking. It is therefore incorrect to equate ETS values with numbers of cigarettes smoked.

If a comparison with active smoking is to be made, the following should be taken into account:

a) The composition of ETS is quantitatively quite different from that of mainstream smoke.

b) The way compounds in ETS are taken up by the body may be different from the way that mainstream smoke components are taken up during active smoking.

c) A given quantity of a compound taken up by the body during a few seconds (active smoking) would be expected to have quite different effects from the same quantity taken up during many hours of ETS exposure.

Taking into account the above comments, the quantities of smoke components inhaled during exposure to ETS have been calculated on the basis of the exposure levels found in this study. These are compared below to the quantities of components inhaled by active smoking. No equivalence of these two forms of exposure is implied.

Two assumptions are made:

A. That adults breathe 1 m^3 of air per hour, ie 24 m^3 of air is inhaled during 24 hours.

B. That a 'typical' UK smoker smokes 15 cigarettes per day, each with a 10 mg nicotine-free dry particulate matter yield and a 1 mg nicotine yield.

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Using these assumptions and the values obtained during this study the following statements can be made:

ETS Particles

- A person smoking 15 cigarettes a day (10 mg particulate matter yield per cigarette) would inhale approximately 150,000 μg of particulate matter during 24 hours.

- A person continually exposed to the median ETS particles level of 2 $\mu g/m^3$ found in this study would inhale approximately 48 μg of these particles during 24 hours. Therefore, it would take this person more than eight years to inhale the quantity of smoke particles that a 'typical' smoker would inhale in one day.

- A person continually exposed to the mean ETS particles level of 12 $\mu g/m^3$ found in this study would inhale approximately 288 μg of these particles during 24 hours. Therefore, it would take this person 521 days to inhale the quantity of smoke particles that a 'typical' smoker would inhale in one day.

- A person continually exposed to the maximum ETS particles level of 159 $\mu g/m^3$ found in this study would inhale approximately 3816 μg of these particles during 24 hours. Therefore, it would take this person 39 days to inhale the quantity of smoke particles that a 'typical' smoker would inhale in one day.

Nicotine

- A person smoking 15 cigarettes a day (1 mg nicotine yield per cigarette) would inhale approximately 15,000 μg of nicotine during 24 hours.

- A person continually exposed to the median nicotine level of 0.5 $\mu g/m^3$ found in this study would inhale approximately 12 μg of nicotine during 24 hours. Therefore, it would take this person more than three years to inhale the quantity of nicotine that a 'typical' smoker would inhale in one day.

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• A person continually exposed to the mean nicotine level of 1.7 $\mu g/m^3$ found in this study would inhale approximately 41 μg of nicotine during 24 hours. Therefore, it would take this person 367 days to inhale the quantity of nicotine that a 'typical' smoker would inhale in one day.

• A person continually exposed to the maximum nicotine level of 26 $\mu g/m^3$ found in this study would inhale approximately 624 μg of nicotine during 24 hours. Therefore, it would take this person 24 days to inhale the quantity of nicotine that a 'typical' smoker would inhale in one day.

The following table summarises these calculations:

	ETS (as SPM)			Nicotine		
	Mean	Median	Maximum	Mean	Median	Maximum
Measured value ($\mu g/m^3$) this study	12	2	159	1.7	0.5	26
Total in 24 hours (μg)	288	48	3816	41	12	624
Time to inhale an amount corresponding to 1 day's typical active smoking	521	> 8 years	39 days	367 days	> 3 years	24 days
Typical smoker 15 cigarettes/day		150,000 μg/day			15,000 μg/day	

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

4.8 Objective 1

To determine the range, mean and median levels of 24 hour exposure to nicotine and ETS particles for non-smoking British volunteers.

To meet this objective, ETS exposure was assessed by the subject answering a questionnaire, by direct measurement using personal monitoring and by measurement of salivary cotinine.

4.8.1 Subjective assessment by questionnaire

Figure 3 shows the subjective assessments of the 24 hour exposure made by all subjects. Approximately 80% of the subjects considered that during the monitoring period their exposure to ETS was either 'none' or 'low'. Only one subject reported exposure as 'very high'.

4.8.2 Direct exposure measurements

From the individual analytical results (See Appendix 6.1) the range, mean and median levels for each analyte were derived for all subjects. These summary data are given in Figure 4.

Figure 5 demonstrates that ETS particles make only a small contribution to PAS. This confirms that there are other significant sources of particles in the atmosphere as well as those from PAS. For this study the mean SPM level as a percentage of PAS for all subjects is 7.1%.

Figure 6 shows how SPM and nicotine results are distributed by subject.

For SPM, more than 70% of the subjects had exposure levels less than 10 $\mu g/m^3$. The mean is 12 $\mu g/m^3$, and the median 2 $\mu g/m^3$.

More than 60% of the subjects were exposed to less than 1 $\mu g/m^3$ nicotine. More than 85% of the subjects were exposed to less than 5 $\mu g/m^3$ nicotine. The mean for nicotine is 1.7 $\mu g/m^3$, and the median 0.5 $\mu g/m^3$.

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

The only subject assessing his ETS exposure as 'very high' had directly measured SPM and nicotine values well above average for the subjects as a whole, but no higher than for many other subjects. This subject's pre cotinine level was 0.6 ng/mL, about the mean for all subjects, but the post cotinine level was 5.7 ng/mL, significantly higher than average, but by no means the highest on the study.

4.8.3 Cotinine level measurements

Figure 7 shows how the data for pre and post cotinine levels are distributed by subject. The graphs show near identical patterns, with both the pre and post mean values at 1.4 ng/mL. The median levels for pre and post cotinine were 0.7 ng/mL and 0.6 ng/mL respectively.

Key analytical data by age and sex are shown in Appendix 6.5. From this table, male subjects had higher mean and median results than women for nicotine, SPM and pre and post cotinine levels.

If age groups are compared the results indicate that the highest median levels of ETS exposure for males and females are in the 21 to 29 age group.

The subjective assessments and the direct measurements indicate that for a large majority of subjects their ETS exposure was either 'none' or at a 'low' level.

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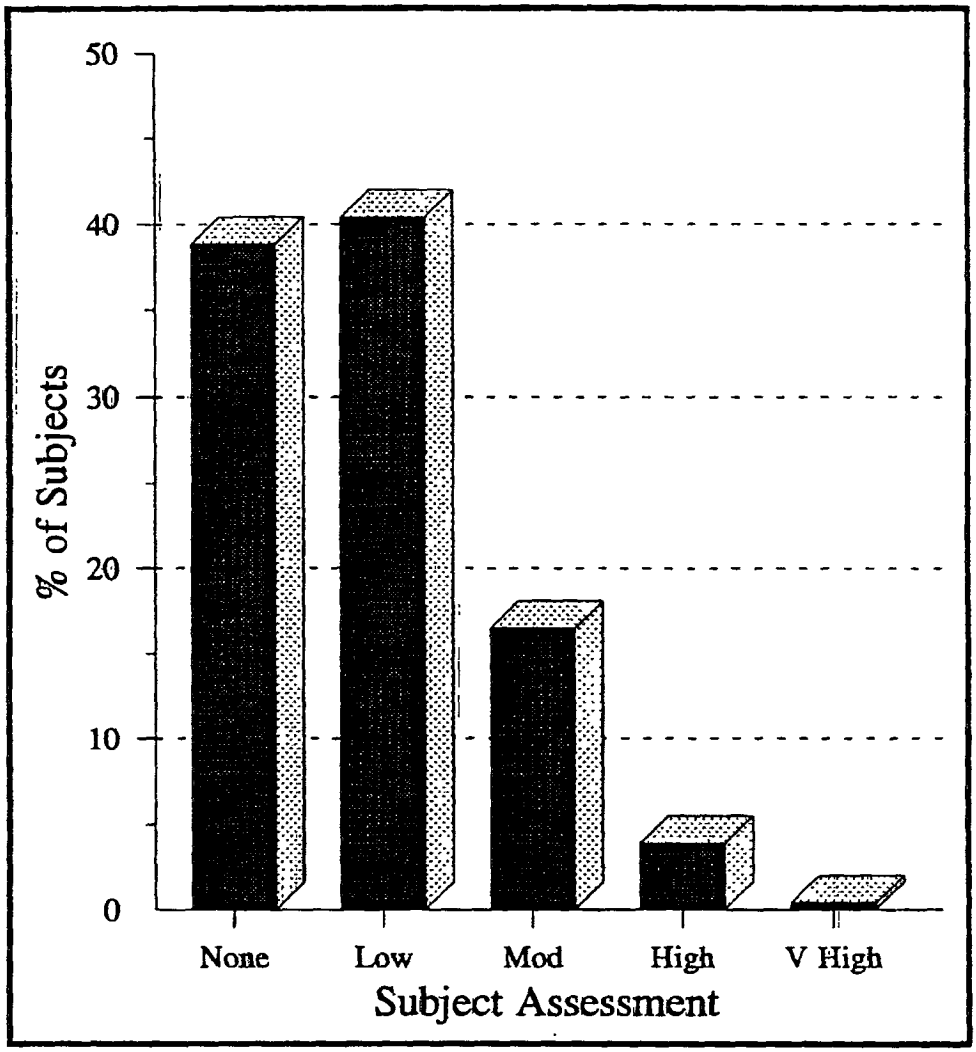
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 3

SUBJECTIVE ASSESSMENT OF AVERAGE EXPOSURE TO ETS DURING MONITORING PERIOD



Overall Number of Subjects = 255

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 4

SUMMARY STATISTICS FOR ALL ANALYTES AND ALL SUBJECTS

		Minimum	Maximum	Mean	Median	No Results
PAS	($\mu g/m^3$)	20	1219	179	142	255
UVPM	($\mu g/m^3$)	4	299	31	21	255
FPM	($\mu g/m^3$)	2	146	16	10	255
SPM	($\mu g/m^3$)	2	159	12	2	255
Nic	($\mu g/m^3$)	0.05	26	1.7	0.50	249
3-eth	($\mu g/m^3$)	0.05	4.2	0.38	0.05	249
Pre Cot	(ng/mL)	0.25	14	1.4	0.7	254
Post Cot	(ng/mL)	0.25	12	1.4	0.6	248

FIGURE 5

SPM AS PERCENTAGE OF PAS

Minimum	0.2	
Maximum	60.0	(255 subjects)
Mean	7.1	
Median	2.5	

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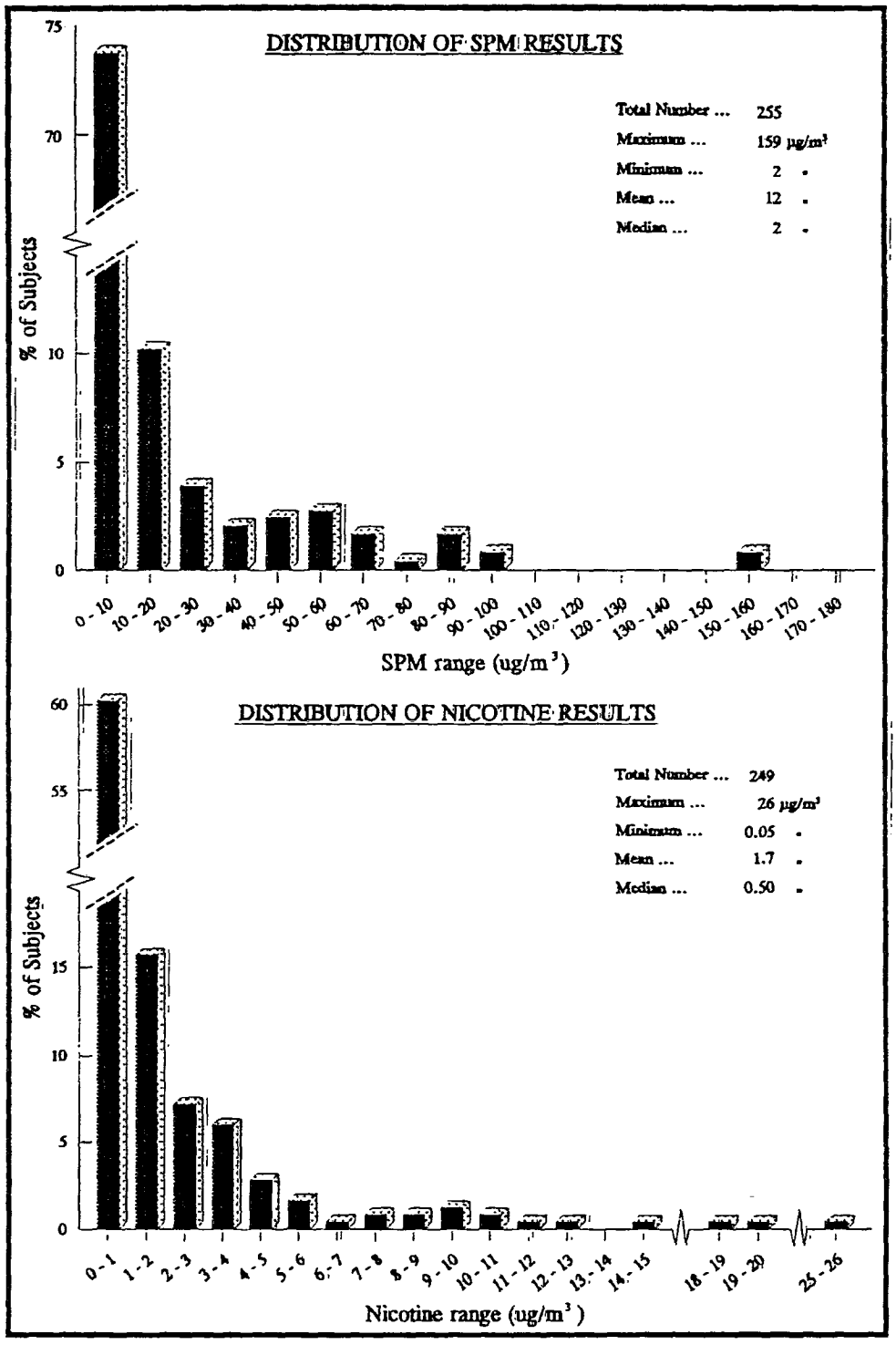
FIGURE 6

DISTRIBUTION OF SPM and NICOTINE RESULTS



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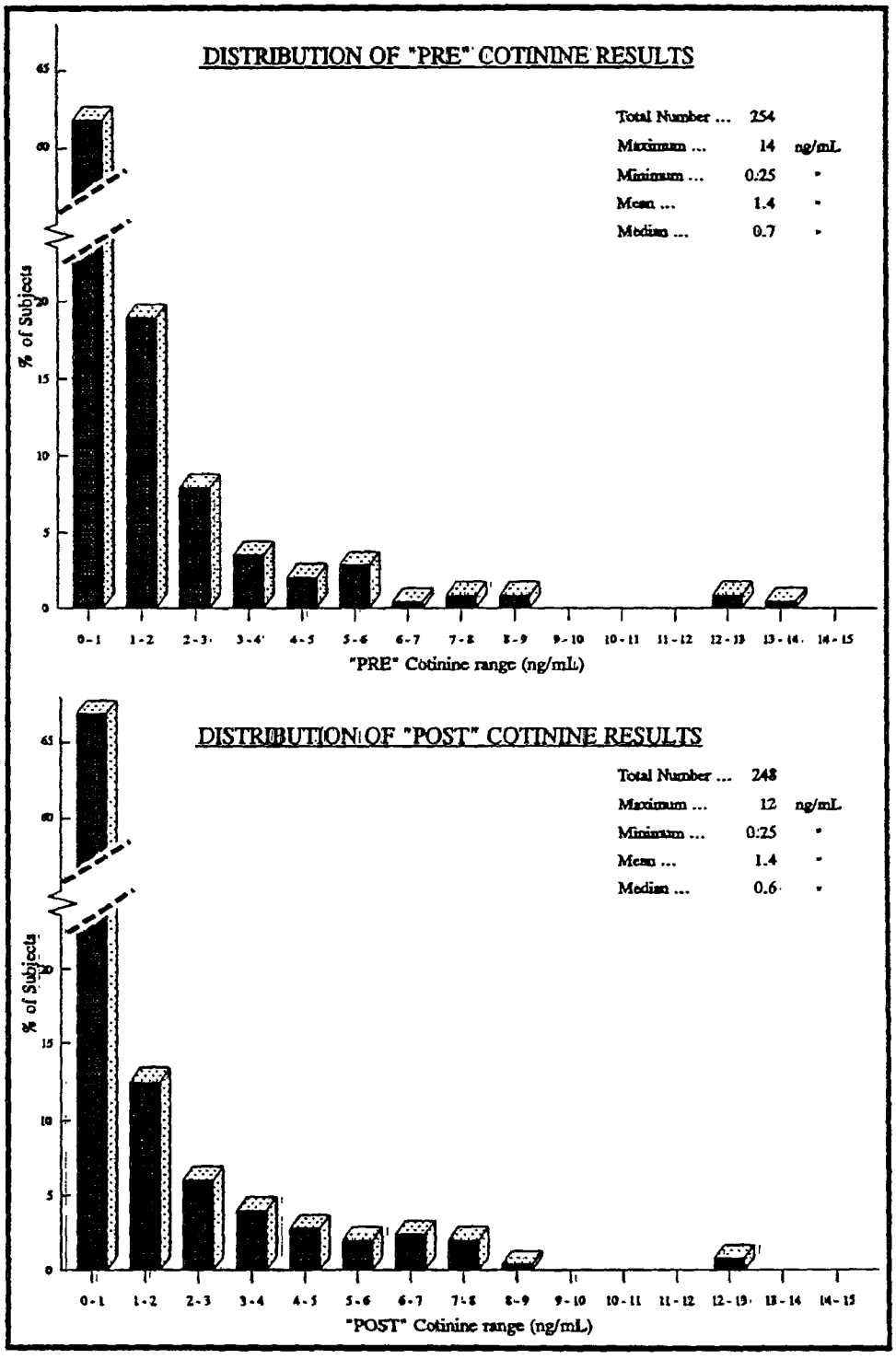
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 7

DISTRIBUTION OF COTININE RESULTS



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4.9 Objective 2

To assess the contributions to total ETS exposure from the home, the workplace, leisure and travel.

Individual contributions to total ETS exposure from the home, workplace, leisure and travel were assessed by questionnaire and by evaluation of 24 hour measurements on those subjects who reported exposure to ETS from only one of these four sources. Computed estimates for all subjects were also made based on a combination of questionnaire and directly measured data.

4.9.1 Subjective assessment by questionnaire

Figure 8 shows the subjective assessments made by subjects of the percentage contributions of the four sources of ETS exposure to their overall exposure. The figure represents data provided by the 156 subjects who claimed some exposure to ETS during the monitoring period.

Figure 9 shows how these assessments are distributed for the monitoring period.

Figure 10 shows a distribution of assessments by all subjects for the previous six months.

These subjective assessments indicate the ranking of sources of exposure is:

LEISURE > WORK > HOME > TRAVEL

These assessments of relative contributions should be considered in combination with the assessments made by all subjects of their level of exposure from each of the four sources. Figure 11 shows the assessments of level of exposure for each of the four sources by subjects who were exposed from that source but not exclusively.

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Figure 12 shows the assessments of level of exposure for three of the four sources by subjects who were exposed from that source exclusively. There are not enough data on Travel (three subjects) to provide meaningful information in this case.

4.9.2 Direct exposure measurements

Contributions to ETS exposure from the home, workplace, leisure and travel were evaluated for those subjects who reported single source exposure exclusively. These were the only subjects for which information about the single sources of exposure could be estimated directly because most subjects were either exposed to no ETS or exposed to more than one source.

Figure 13 shows the summary for measured exposure levels of SPM and nicotine and the number of subjects involved.

Figures 14 and 15 show how these data are distributed for SPM and nicotine respectively.

Results for the direct measurements indicate that for both SPM and nicotine the ranking is:

HOME > LEISURE > WORK

4.9.3 Computed exposure estimates

In view of the small numbers of subjects in these groups, another approach was used to assess the home, workplace, leisure and travel contributions to total ETS exposure for all subjects.

Each subject's estimate of relative exposure from the four different sources (Question 17) was used in order to distribute the corresponding measured overall exposure throughout the four sources. Where the subjects rated

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their average ETS exposure to be 'none' (Question 15) then the corresponding measured levels were distributed according to the number of hours the subject spent by source (Questions 21 to 24).

Figure 16 shows the summary exposure levels computed on this basis.

It is difficult to assess the relative ETS contributions on the basis of median results as the values are so low. However, the mean results for the measured and computed data sets suggest that the magnitude of contributions is:

HOME > LEISURE > WORK > TRAVEL

Part of the explanation for this ranking is undoubtedly the amounts of time spent in these situations. For most people, the majority of their time is spent at home whereas travel occupies only a small part of their time.

It is interesting that the ranking of the directly measured exposures is different from the ranking perceived by the subjects. One possible explanation for this is that subjects have based their judgements on the relative ETS levels in the four situations while neglecting the amount of time spent in these situations.

The directly measured results indicate that the ranking of relative contributions to total ETS exposure is HOME > LEISURE > WORK > TRAVEL. Subjective assessments appear to overestimate the contributions from leisure and the workplace to total exposure. Both subjective assessment and direct measurements indicate that travel makes a very small contribution to overall exposure.

The large majority of subjects regard the exposure level from each of the four sources as 'none' or 'low'. This is consistent with the direct measurements of exposure.

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FIGURE 8

PERCENT RELATIVE CONTRIBUTIONS TO OVERALL ETS EXPOSURE

(SUBJECTIVE)

	Monitoring period	Last six months
Home	27.8	19.8
Work	31.5	29.4
Leisure	35.1	46.3
Travel	5.7	4.7

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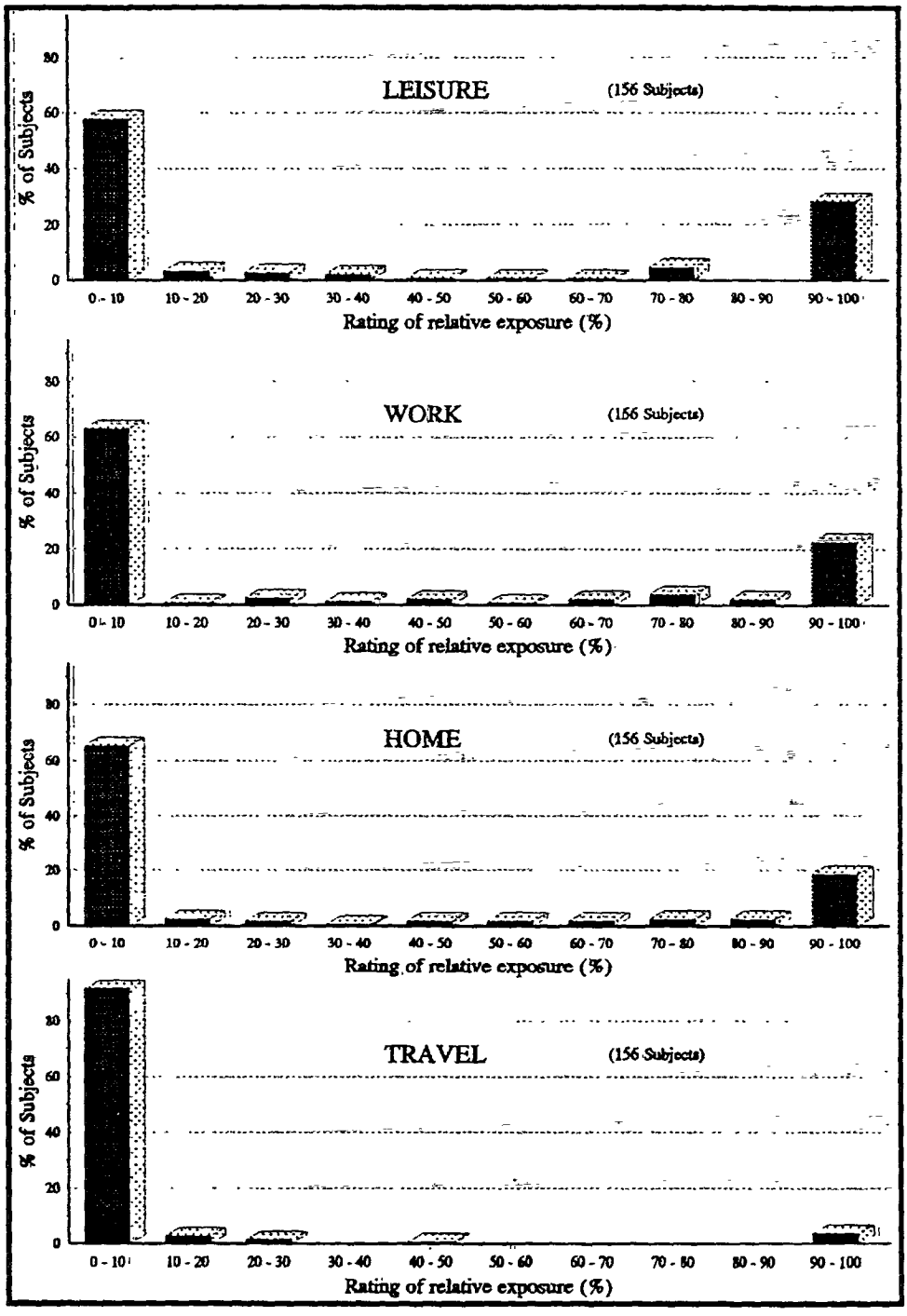
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 9

SUBJECTIVE ASSESSMENT OF RELATIVE PERCENTAGE ETS EXPOSURE BY SOURCE (MONITORING PERIOD)



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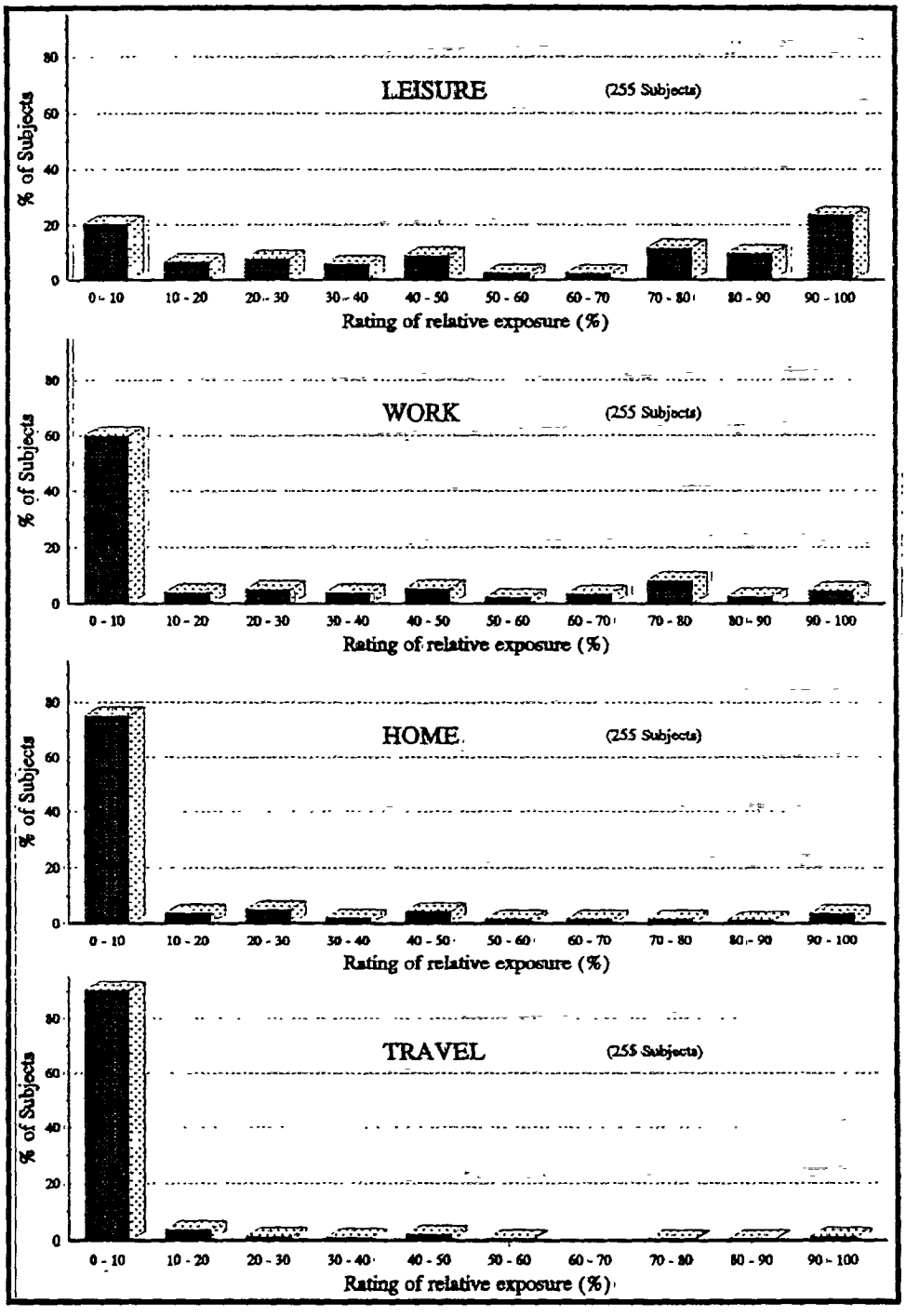
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 10

SUBJECTIVE ASSESSMENT OF RELATIVE PERCENTAGE ETS EXPOSURE BY SOURCE (LAST 6 MONTHS)



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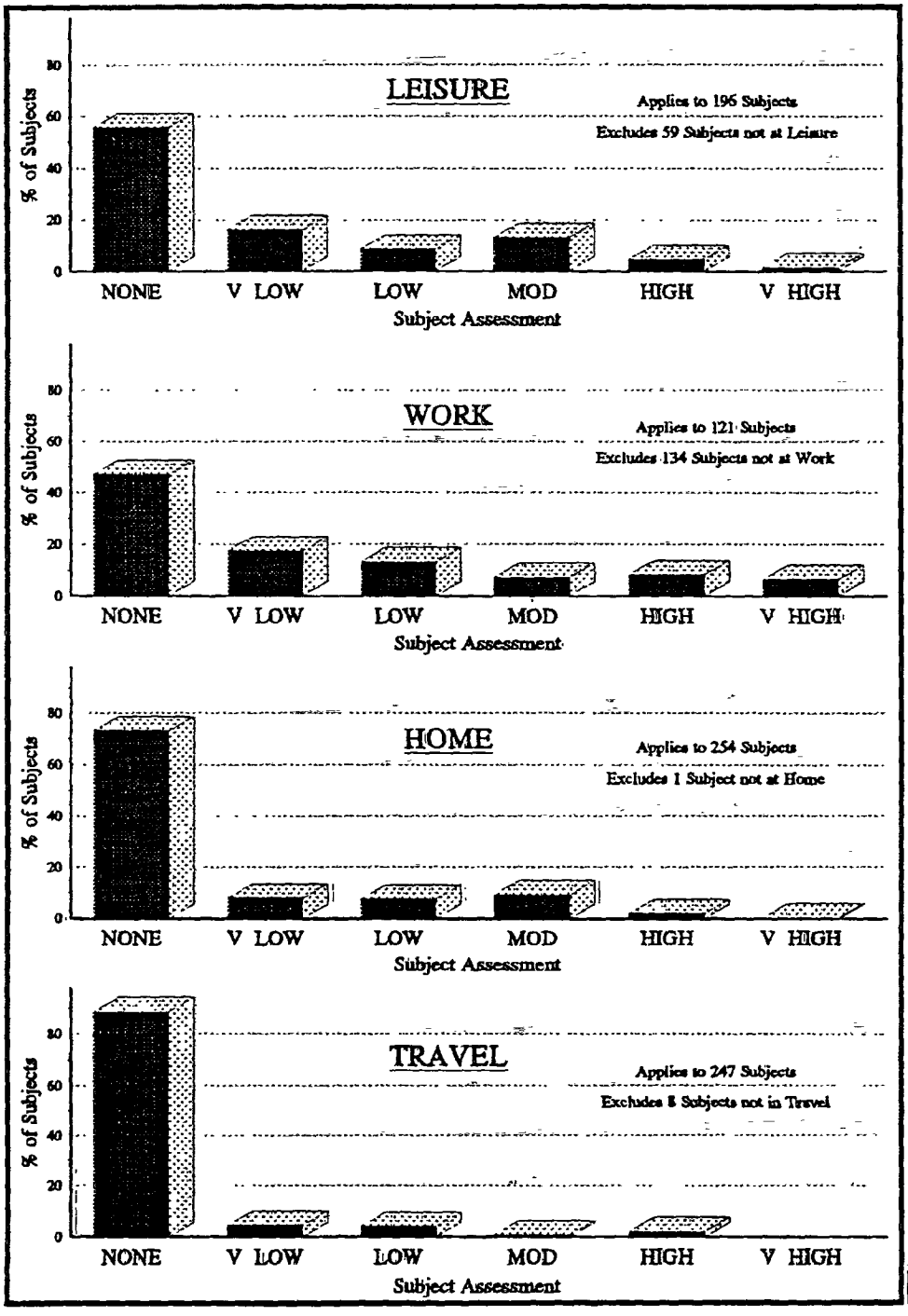
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 11

SUBJECTIVE ASSESSMENT OF ETS EXPOSURE BY SOURCE DURING MONITORING PERIOD



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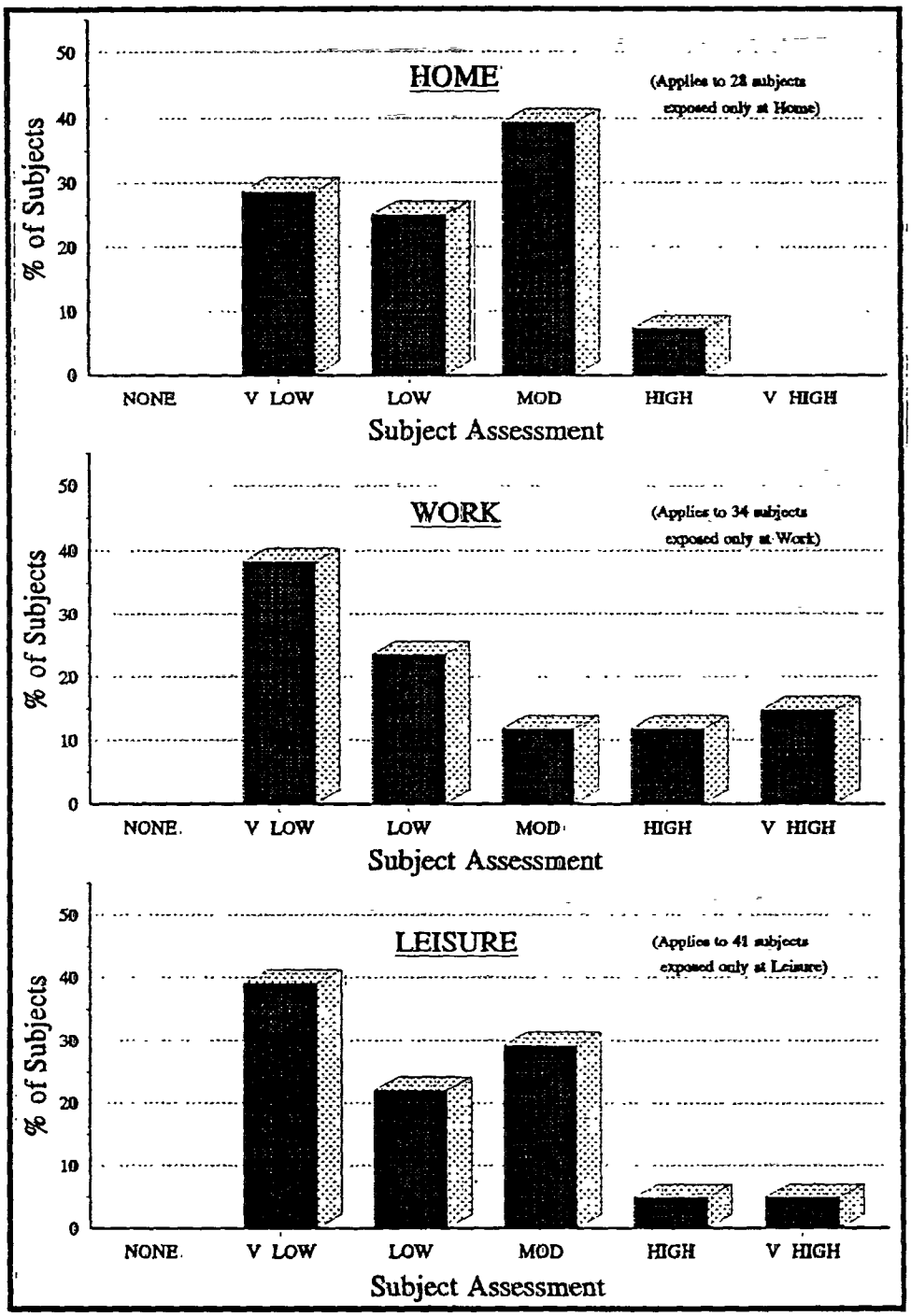
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 12

SUBJECTIVE ASSESSMENT OF ETS EXPOSURE DURING MONITORING PERIOD (ONLY "SINGLE SOURCE" SUBJECTS)



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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 13

MEASURED EXPOSURE AT HOME, WORKPLACE, LEISURE AND TRAVEL

		Number	Maximum	Minimum	Mean	Median
Home		28	70	2	18	7
Workplace	SPM	34	44	2	6	2
Leisure	$\mu g/m^3$	41	64	2	10	2
Travel		3	2	2	2	2
Home		28	11	0.05	2	1.2
Workplace	Nicotine	34	5.6	0.05	1.1	0.57
Leisure	$\mu g/m^3$	39	9.2	0.05	1.4	0.72
Travel		3	0.63	0.21	0.4	0.35

These results are for subjects reporting exposure from only one of the four sources.

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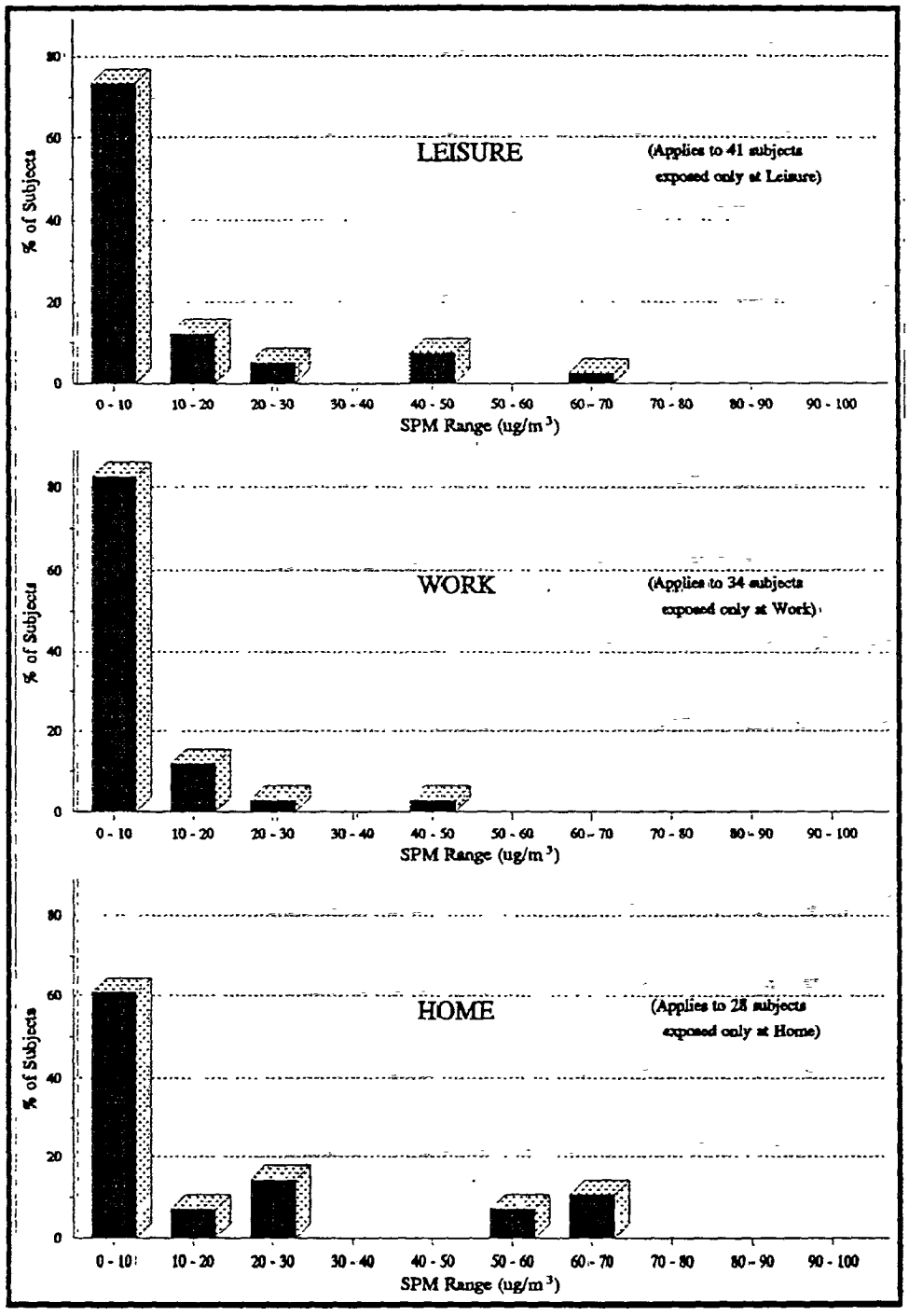
FIGURE 14

DISTRIBUTION OF SPM RESULTS BY SOURCE

(SUBJECTS ASSESSING EXPOSURE AS SINGLE SOURCE)



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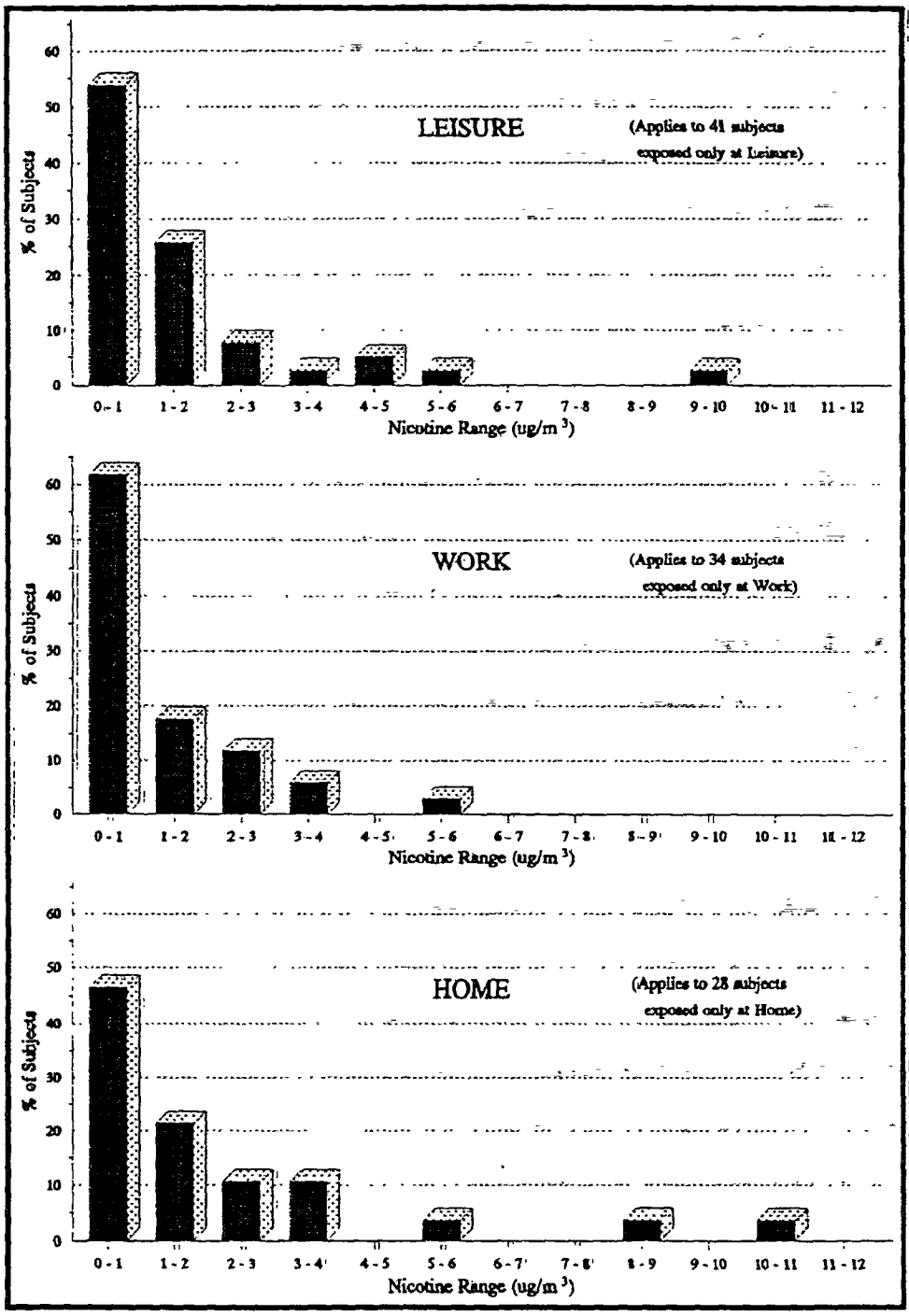
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 15

DISTRIBUTION OF NICOTINE RESULTS BY SOURCE

(SUBJECTS ASSESSING EXPOSURE AS SINGLE SOURCE)



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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 16

"COMPUTED" ESTIMATES FOR KEY ANALYTES BY SOURCE

	Maximum	Mean	Median	
Home	107.2	5.73	1.46	
Work	78.6	2.60	0.00	SPM
Leisure	11.0	0.41	0.00	$\mu g/m^3$
Travel	151.2	3.75	0.08	
Home	15.5	0.76	0.04	
Work	9.7	0.39	0.00	Nicotine
Leisure	2.1	0.06	0.00	$\mu g/m^3$
Travel	24.3	0.54	0.00	

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

4.10 Objective 3

To assess whether non-smokers who are married to smokers have significantly higher exposures to ETS than non-smokers married to non-smokers.

To address this objective the 255 subjects were divided into three groups as follows:

	Number in group
Subjects with no spouse or partner	74
Subjects with a non-smoking spouse or partner	133
Subjects with a smoking spouse or partner	48

4.10.1 Subjective assessment by questionnaire

Figure 17 shows the subjective assessments of 24 hour exposure made by the three groups.

Although there is clearly an overlap in the assessments made by the three groups the results suggest that the ranking of exposure is

SMOKING SPOUSE OR PARTNER > NO SPOUSE OR PARTNER > NON-SMOKING SPOUSE OR PARTNER

4.10.2 Direct measurements and salivary cotinine levels

The directly measured exposure levels and the salivary cotinine results for these three groups of subjects are summarised in Figure 18 and Figure 20 respectively.

Figure 19 shows the distributions of the SPM results for these subject groups. These show a similar pattern to the subjective assessments.

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Again, the ranking of exposure levels is:

SMOKING SPOUSE OR PARTNER > NO SPOUSE OR PARTNER > NON-SMOKING SPOUSE OR PARTNER

Epidemiolbgical studies related to ETS exposure have used the criterion of a spouse that smokes as an index of ETS exposure. The mean exposure levels for subjects with a smoking spouse or partner were greater than for those with a non-smoking spouse or partner. However, the distributions of results show that there is not a clear distinction between the two groups and that there is a substantial overlap between the ranges in both the subjective and the measured results. Furthermore 46% of subjects with a smoking spouse/partner assessed their ETS exposure as 'none' or 'low'. This is supported by direct measurements. Also, approximately 30% of subjects with a smoking spouse/partner assessed leisure or work as their principal source of exposure.

Clearly the criterion of a smoking spouse or partner should not be used, without supplementary evidence, when assessing ETS exposure of individual subjects.

Statistical evaluation of the results using non parametric methods is shown in Figure 21. The results show that the differences in the ETS exposure levels for these subject groups are significant. There were, however, no significant differences in PAS exposure between these groups.

The exposure levels of the group of subjects with a smoking spouse or partner is significantly higher than that of subjects with non-smoking spouses or partners. However there is considerable variation in the exposure of individual subjects within these groups as well as overlap between the groups. It is recommended that spouse or partner smoking status should only be used in combination with supplementary information when assessing ETS exposure.

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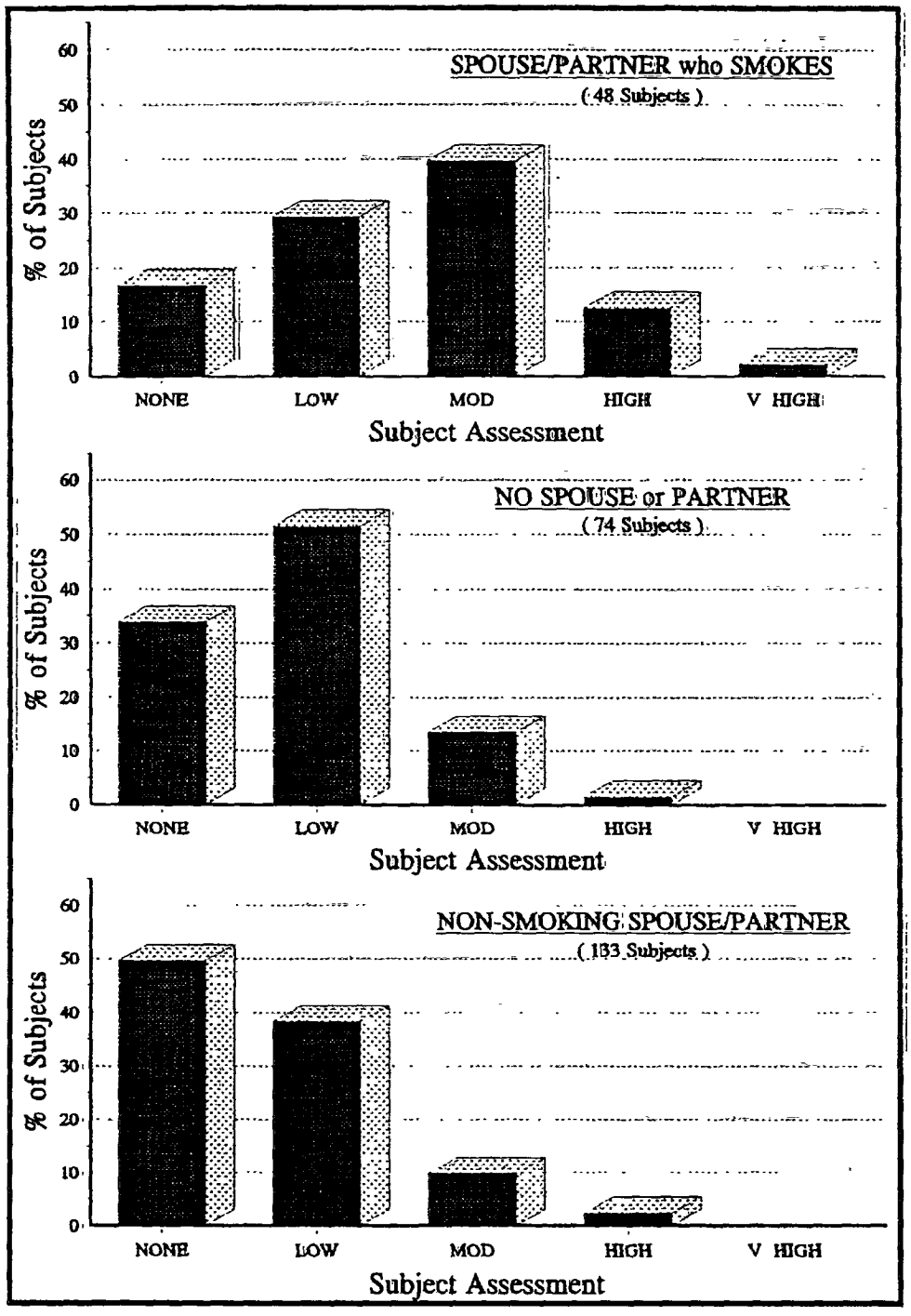
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 17

SUBJECTIVE ASSESSMENT OF AVERAGE ETS EXPOSURE ACCORDING TO SPOUSE'S SMOKING HABITS



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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 18

SUMMARY OF PAS, SPM AND NICOTINE LEVELS FOUND BY CLASSIFICATION OF SPOUSE OR PARTNER

		Number	Minimum	Maximum	Mean	Median
Overall	PAS ($\mu g/m^3$)	255	20	1219	179	142
NS Partner	"	133	20	995	166	129
SM Partner	"	48	48	1219	219	161
No Partner	"	74	35	539	178	143
Overall	SPM ($\mu g/m^3$)	255	2	159	12	2
NS Partner	"	133	2	159	7	2
SM Partner	"	48	2	153	29	17
No Partner	"	74	2	97	12	2
Overall	Nic ($\mu g/m^3$)	249	0.05	26	1.7	0.50
NS Partner	"	130	0.05	26	1.1	0.28
SM Partner	"	47	0.05	18	4.0	2.5
No Partner	"	72	0.05	19	1.5	0.55

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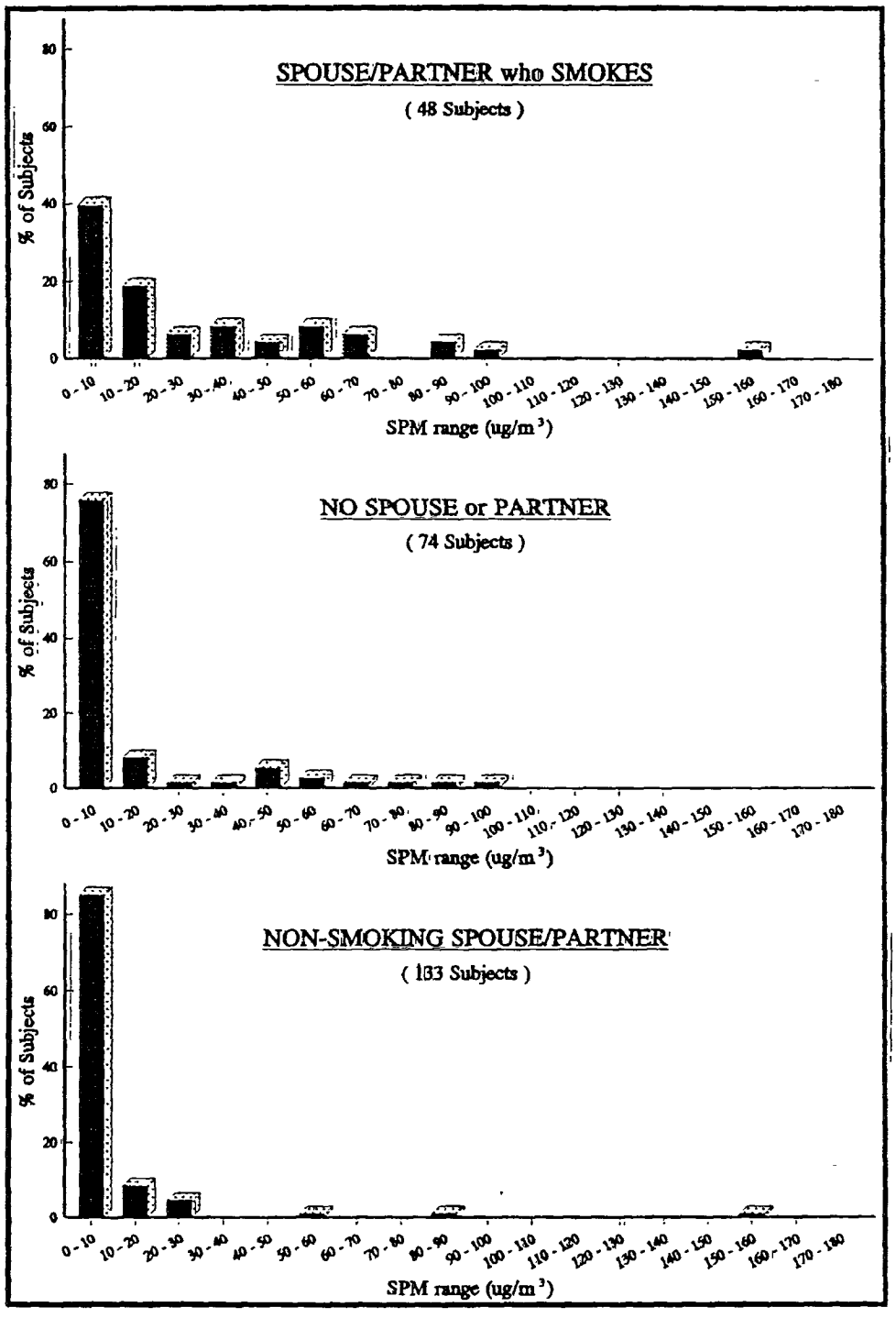
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 19

DISTRIBUTION OF SPM RESULTS ACCORDING TO TO SPOUSE'S SMOKING HABITS



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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 20

SUMMARY OF PRE AND POST COTININE LEVELS FOUND BY CLASSIFICATION OF SPOUSE OR PARTNER

		Number	Minimum	Maximum	Mean	Median
Overall	Pre Cotinine (ng/mL)	254	0.25	14	1.4	0.7
NS Partner	"	132	0.25	8.2	0.83	0.25
SM Partner	"	48	0.25	13	2.3	1.4
NO Partner	"	74	0.25	14	1.8	1.0
Overall	Post Cotinine (ng/mL)	248	0.25	12	1.4	0.6
NS Partner	"	128	0.25	12	0.99	0.25
SM Partner	"	47	0.25	8.1	2.2	1.5
NO Partner	"	73	0.25	12	1.7	0.6

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 21

SUMMARY OF STATISTICAL DIFFERENCES

	NS vs SM	NS vs NP	SM vs NP
SPM	***	**	***
Nicotine	***	*	***
Pre-cotinine	***	***	**
Post-cotinine	***	**	**

* $P < 0.05$
** $P < 0.01$
*** $P < 0.001$
NS = Non smoking spouse or partner
SM = Smoking spouse or partner
NP = No spouse or partner

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

4.11 Objective 4

To compare questionnaires, direct measurements and salivary cotinine levels as methods of assessing exposure to ETS.

To meet this objective various direct measurements, using the personal monitor, will be compared with each other, with the salivary cotinine levels and with the subjective assessments. Direct measurements by personal monitoring are assumed to provide the most reliable estimate of ETS exposure.

4.11.1 Subjective assessments compared with Direct Measurements

Figure 22 shows the relationship between subjects' assessments of their ETS exposure during the monitoring period and the corresponding direct measurements of SPM and nicotine.

As expected, there is a tendency for measured exposure to increase with higher subjective assessments. The majority of subjects can estimate an exposure of 'none' quite well, but there is a considerable variation between direct measurements at higher assessed levels and considerable overlap in the measured exposures for the various grades of subjective assessments.

Some subjects reported their exposure as 'high' but had less directly measured exposure to ETS than some subjects who reported their exposure as 'low'. Clearly, an individual's ETS exposure cannot reliably be estimated by a simple subjective question about levels of exposure.

4.11.2 Subjective assessments compared with salivary cotinine measurements

Figure 23 shows the relationship between subjects' assessments of their ETS exposure during the monitoring period and the corresponding measured levels of salivary cotinine at the start and end of the monitoring period. The relationships for pre and post cotinine levels are similar.

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Again there is a trend towards an increase in measured exposure with higher subjective assessments.

It should be noted that some subjects had relatively high levels of salivary cotinine even though they reported their ETS exposure as 'none'. Furthermore, some subjects had low cotinine levels when they reported their ETS exposure as 'moderate' or 'high'. These findings raise doubts concerning the use of salivary cotinine measurements at low levels for ETS exposure assessment. These concerns have also been expressed by other authors (Proctor et al 1991).

4.11.3 Salivary cotinine levels compared with direct measurements

Figures 24A and B are scatter diagrams of measured exposure to SPM against salivary cotinine level with logarithmic and linear plots respectively. Best fit straight lines are drawn in each case.

There is very poor correlation between these two methods of assessing ETS exposure with R-square values of 0.06 and 0.14 for pre and post cotinine respectively.

Figures 25A and B are scatter diagrams of measured exposure to nicotine against salivary cotinine level with logarithmic and linear plots respectively.

The R-square values are 0.07 and 0.13 for pre and post-cotinine respectively.

The poor correlation is surprising because it was expected that salivary cotinine levels would be dependent on exposure to nicotine.

Some subjects who had been exposed to reasonably high levels of SPM and nicotine had no detectable salivary cotinine. Other subjects who had not

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been exposed to any measurable quantity of nicotine had relatively high levels of salivary cotinine. These poor correlations of salivary cotinine level with measured exposure to SPM and nicotine cast further doubt on the value of salivary cotinine measurements.

4.11.4 Comparison of direct measurements

Figures 26A and B are plots of SPM values against nicotine values and against PAS values. Again the logarithmic plots (A) and linear plots (B) are shown with best fit straight lines. The R-square for nicotine = 0.66 and for PAS = 0.04.

Nicotine and SPM are generated together and there is moderate correlation between them. However, nicotine is known not to be associated with ETS particles and the ratio of nicotine to ETS particles changes as a function of dilution and time (Nelson et al 1992).

SPM levels are not expected to be related to PAS and this is shown to be the case on this study.

Figure 27A and B are plots of SPM values against UVPM values and against FPM values with logarithmic and linear plots respectively. The R-square values are 0.19 for UVPM and 0.46 for FPM which indicates a limited correlation with SPM. However, there appears to be a much better correlation for many of the results, but this is detracted from by high results for UVPM or FPM when SPM is low. This illustrates the lack of specificity of the UV and fluorescence measurements.

Figure 28 summarises the comparison of cotinine and direct measurements and shows only moderate correlation for SPM with both nicotine and FPM.

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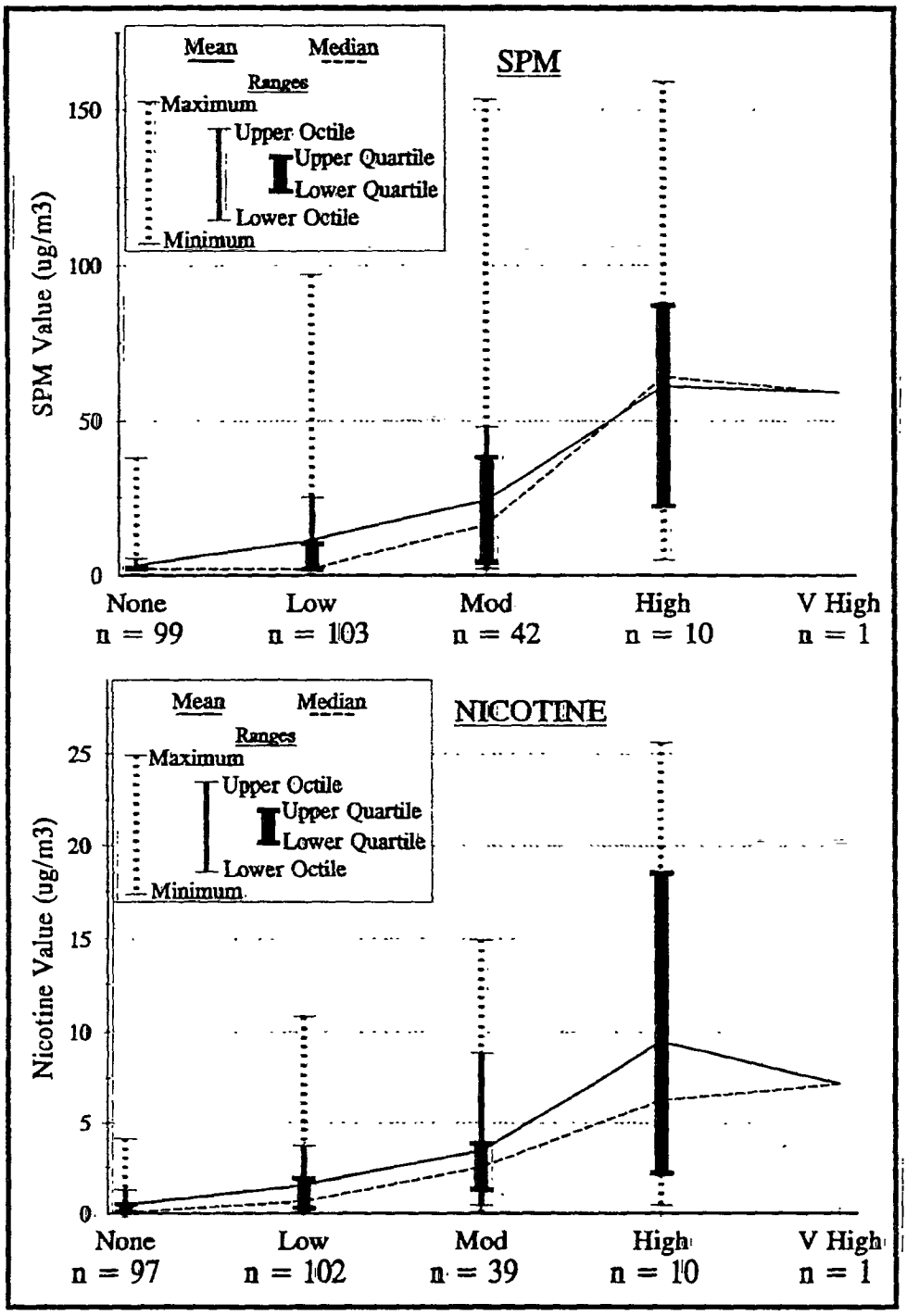
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 22

CORRELATION OF SPM and NICOTINE RESULTS AGAINST OVERALL SUBJECTIVE ASSESSMENT OF ETS EXPOSURE



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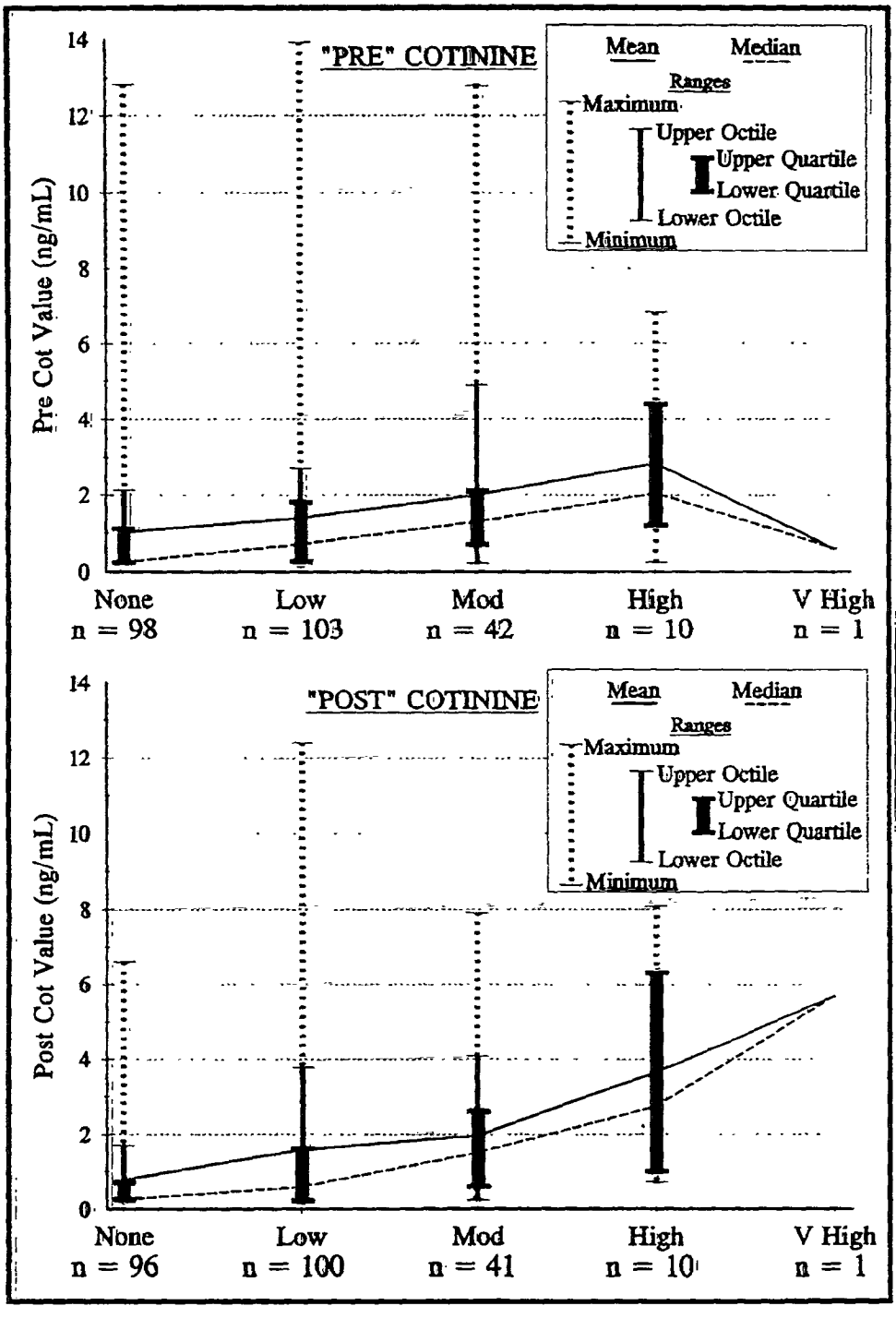
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 23

CORRELATION OF COTININE RESULTS AGAINST OVERALL SUBJECTIVE ASSESSMENT OF ETS EXPOSURE



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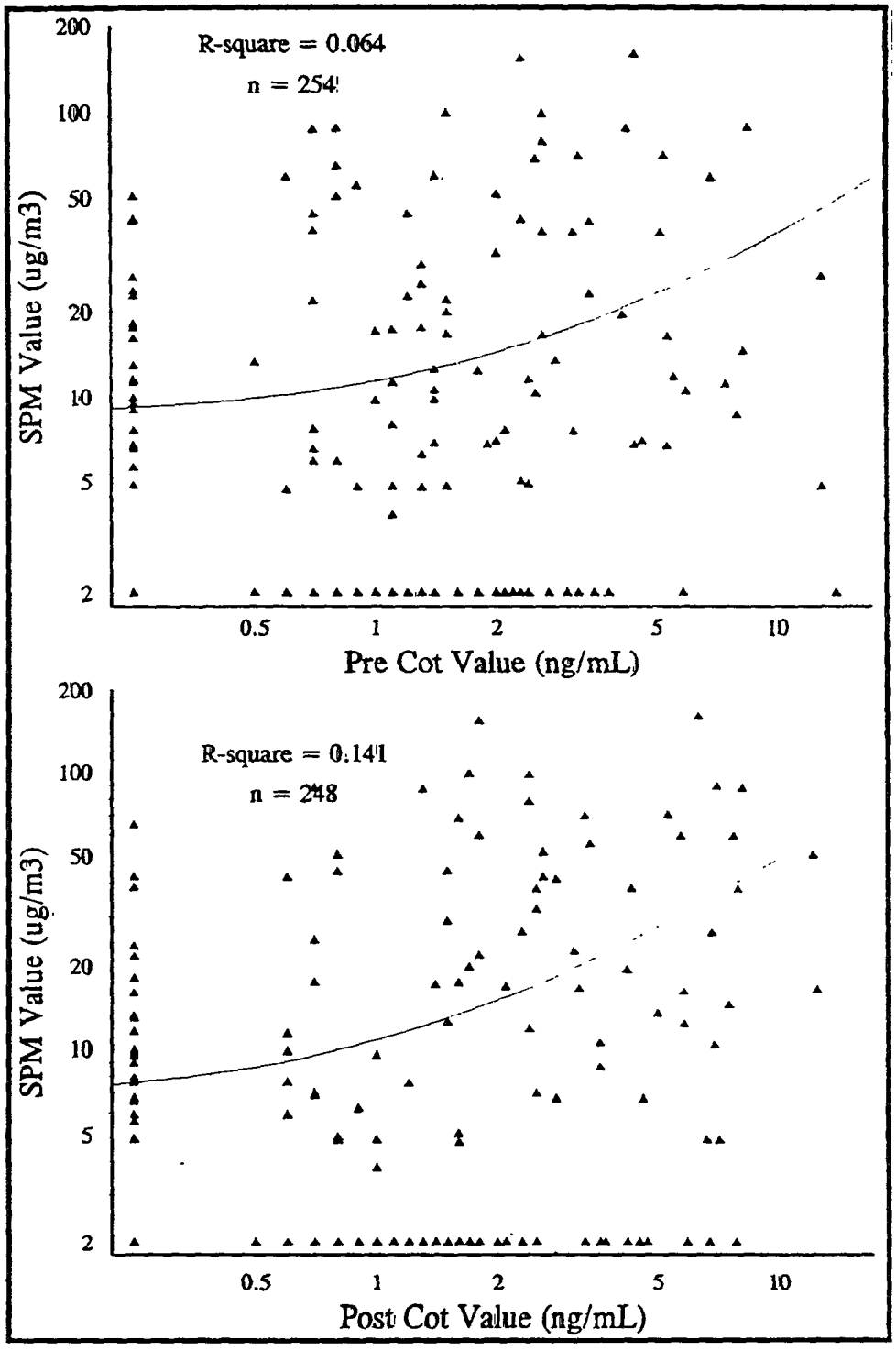
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

HUK Study no 12/64

FIGURE 24A

CORRELATION OF SPM RESULTS WITH COTININE



Logarithmic plot

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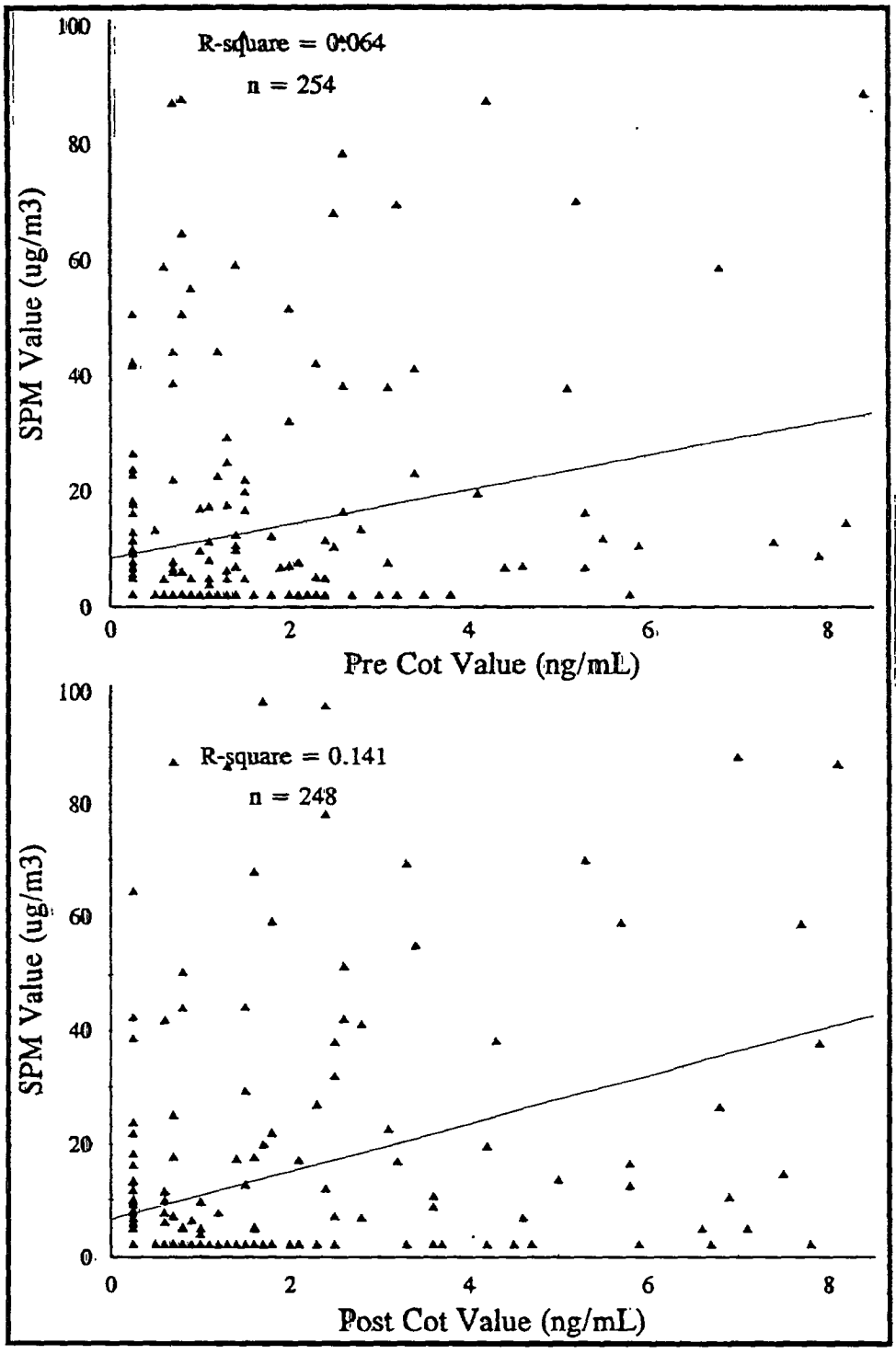
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 24B

CORRELATION OF SPM RESULTS WITH COTININE



Linear plot

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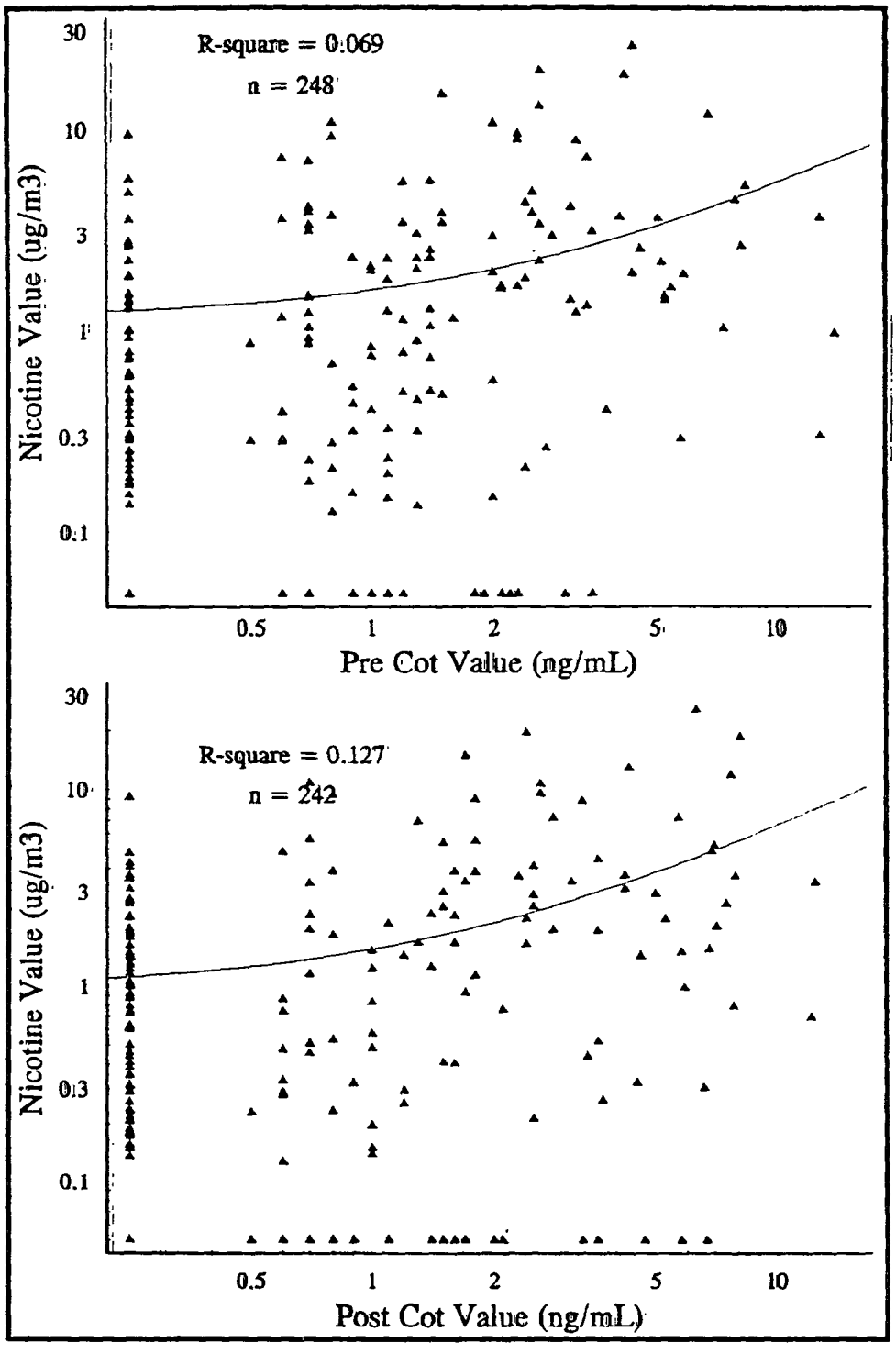
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 25A

CORRELATION OF NICOTINE RESULTS WITH COTININE



Logarithmic plot

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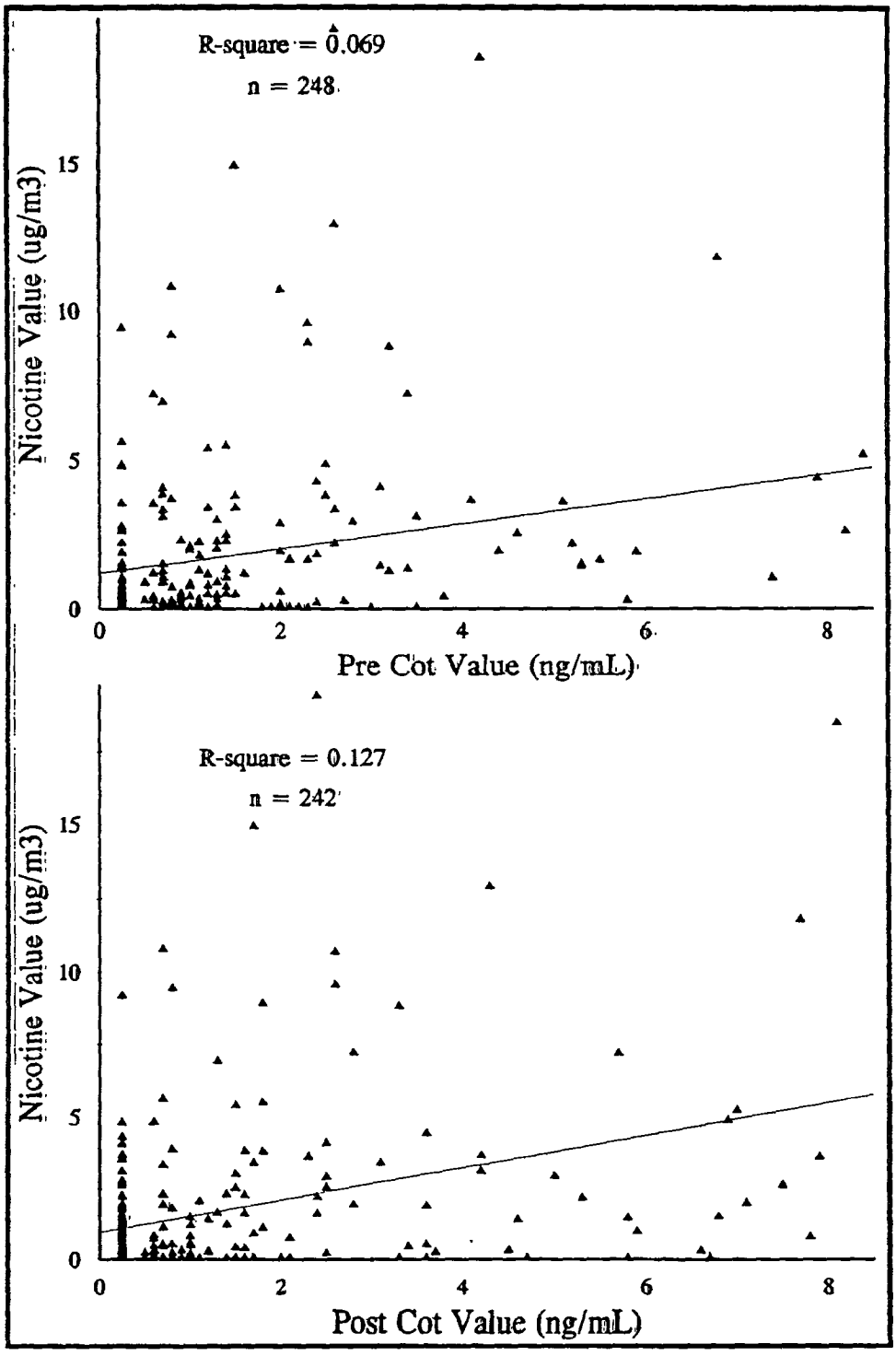
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 25B

CORRELATION OF NICOTINE RESULTS WITH COTININE



Linear plot

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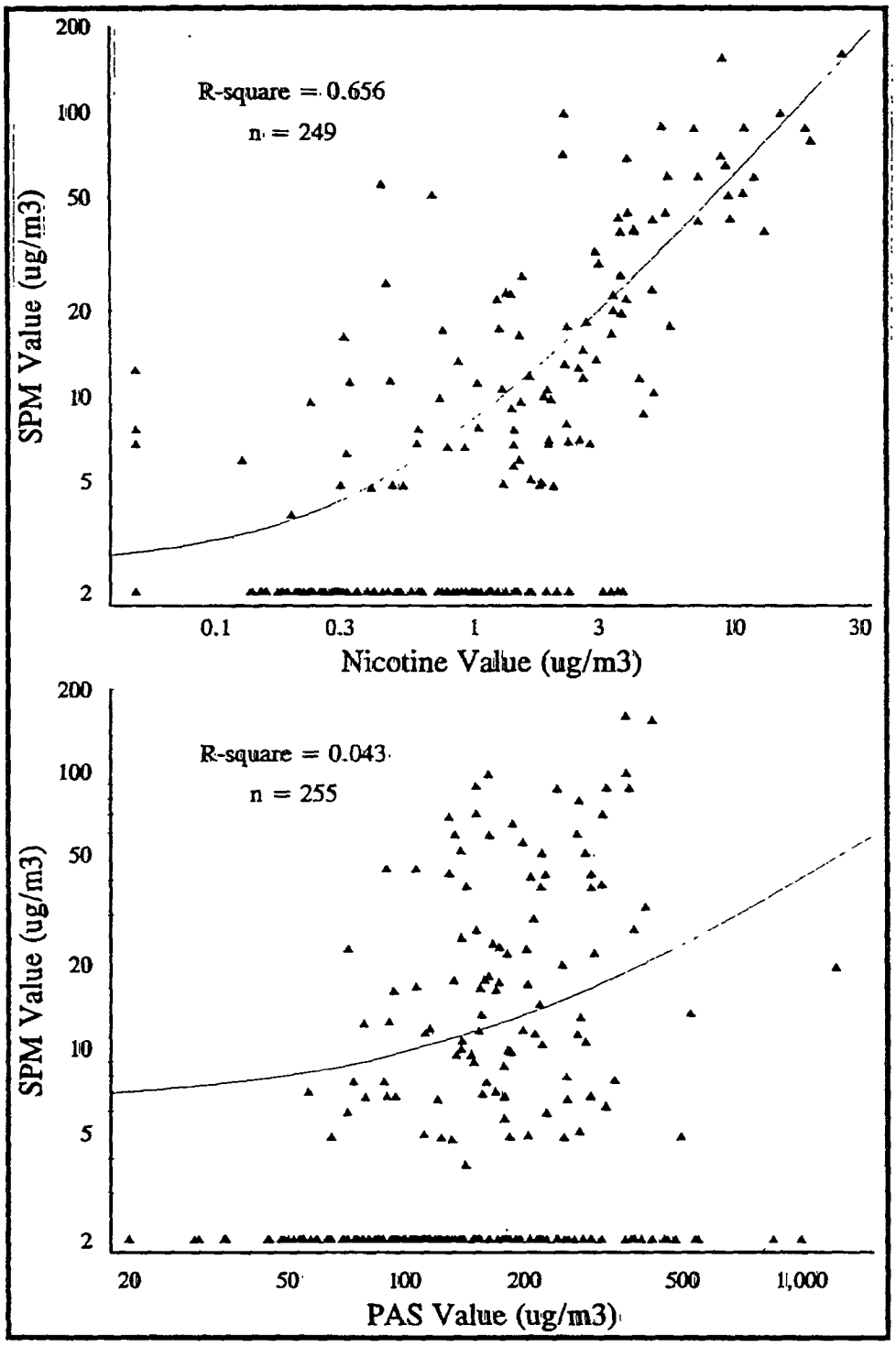
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 26A

CORRELATION OF SPM RESULTS WITH NICOTINE and PAS



Logarithmic plot

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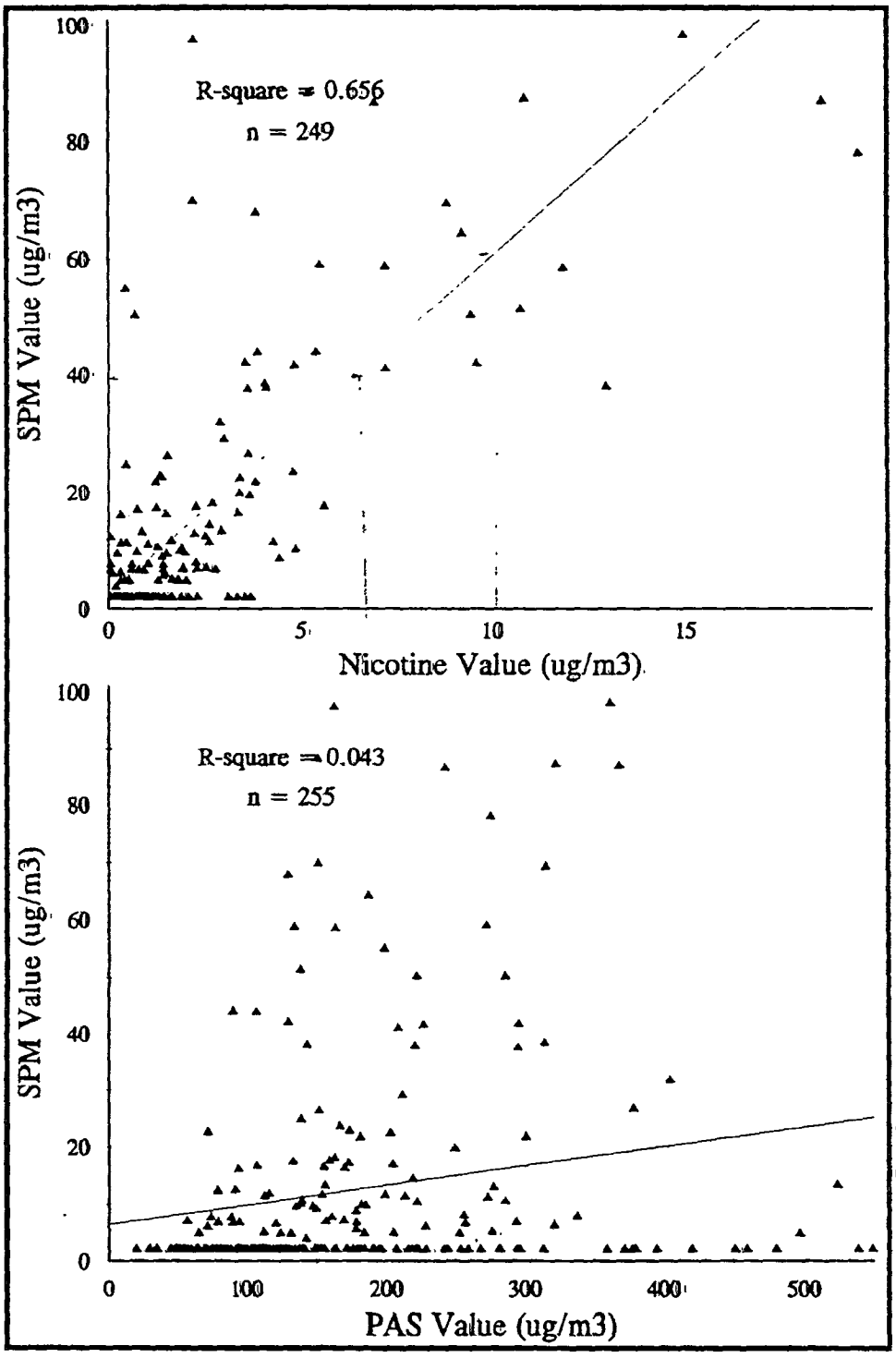
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 26B

CORRELATION OF SPM RESULTS WITH NICOTINE and PAS



Linear plot

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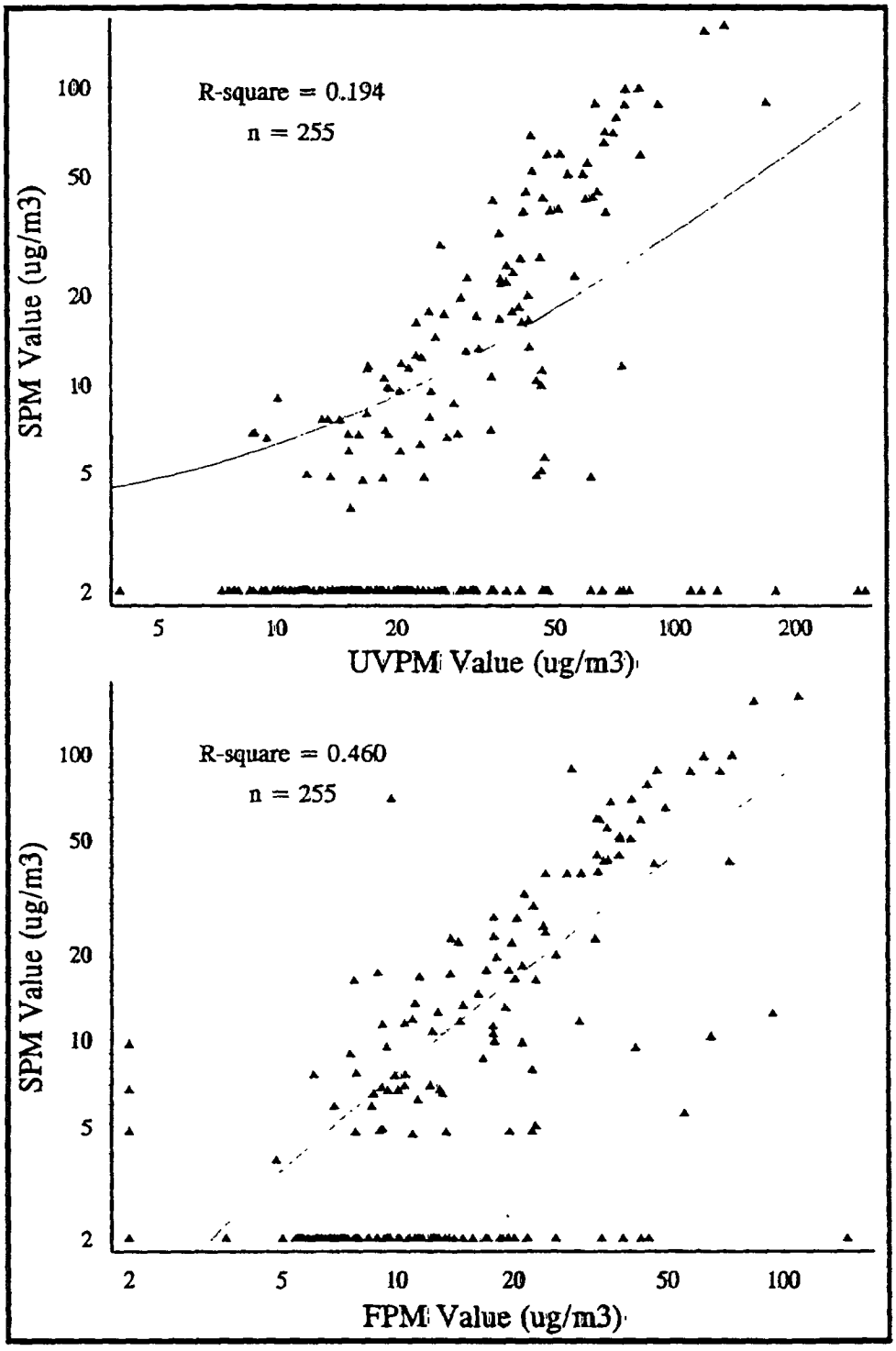
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 27A

CORRELATION OF SPM RESULTS WITH UVPM and FPM



Logarithmic plot

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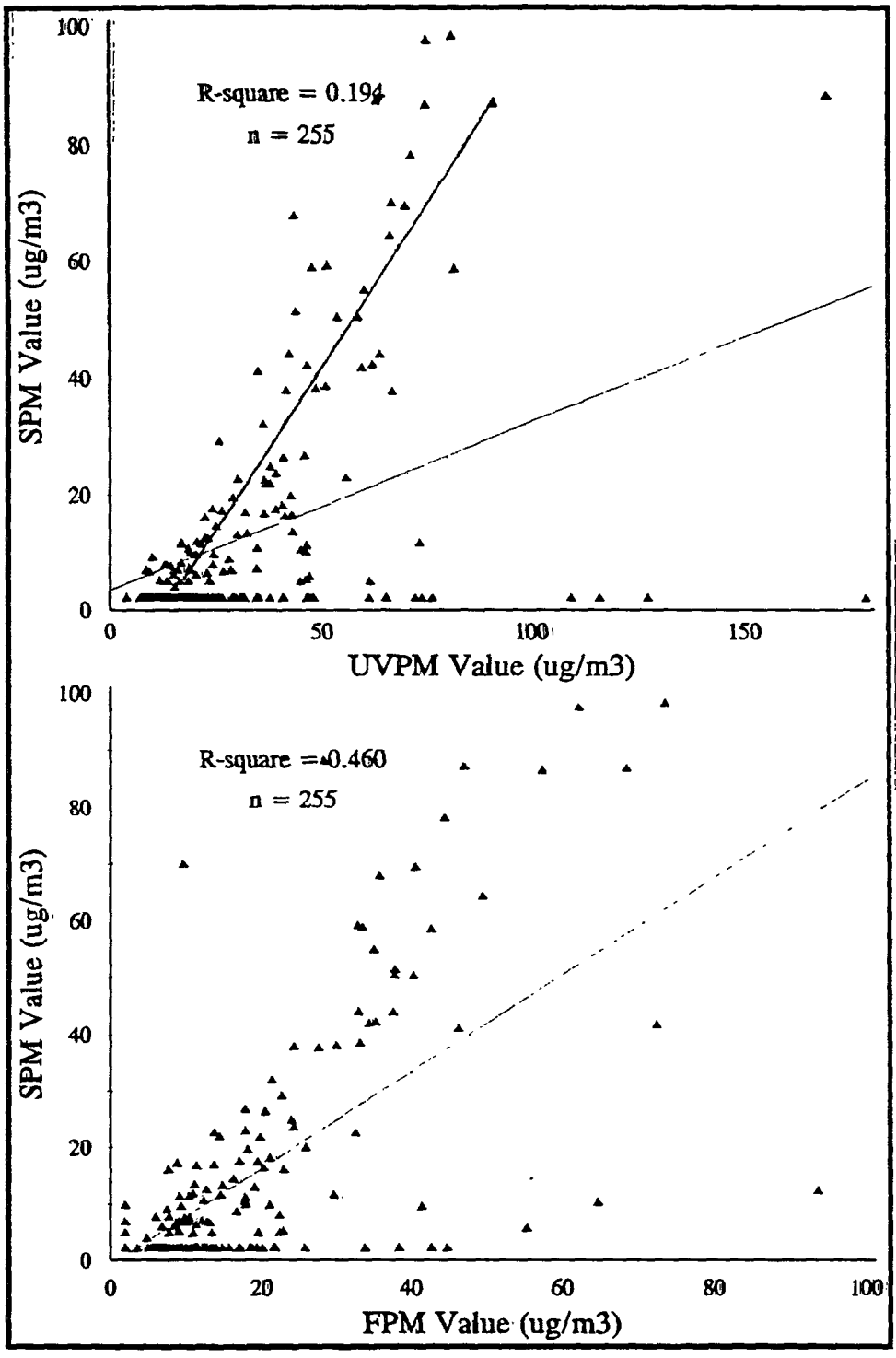
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 27B

CORRELATION OF SPM RESULTS WITH UVPM and FPM



Linear plot

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 28

CORRELATION STATISTICS COMPARING COTININE LEVELS WITH OTHER ANALYTES

Comparison	Number of subjects	Correlation	R-square	Figure number
SPM with pre-cotinine	254	0.25	0.06	24A + B
SPM with post-cotinine	248	0.38	0.14	24A + B
Nicotine with pre-cotinine	248	0.26	0.07	25A + B
Nicotine with post-cotinine	242	0.36	0.13	25A + B
SPM with nicotine	249	0.81	0.66	26A + B
SPM with PAS	255	0.21	0.04	26A + B
SPM with UVPM	255	0.44	0.19	27A + B

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

4.12 Other observations and findings

The following items were not main objectives in this study but are of specific interest.

4.12.1 Leeds and Harrogate

Leeds is a large industrial city in comparison to the rural surroundings and non-industrial area encompassing the North Yorkshire spa town of Harrogate.

A. Subjective assessment

Figure 29 shows the subjective assessments of general air quality made by the subjects living and working in Leeds compared with those subjects living and working in Harrogate. The results show that for Leeds just over 5% thought the air quality was very good compared to almost 25% in Harrogate. Similarly just over 40% in Leeds thought the air quality was good compared to almost 60% in Harrogate. Significantly more than 10% in Leeds thought their air quality was poor with 1 to 2% claiming it was very poor. For Harrogate no one claimed very poor air quality with 1 to 2% claiming a rating of poor.

B. Direct measurement

Figure 30 shows the range mean and median levels of PAS and SPM found for subjects living and working in Leeds (Number 127) and those living and working in Harrogate (115). The remaining 13 subjects did not live and work in the same area.

The mean and median values for PAS indicate a noticeable significant bias towards Leeds in terms of higher PAS levels. Interestingly the SPM levels and SPM as a percentage of PAS are all higher for Leeds than Harrogate.

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

4.12.2 Primary sources of exposure to ETS by subjective assessment

Each subject was asked to assess their own principal sources of exposure to ETS in the six months prior to the start of the study (Question 20). They were asked to provide their four main choices and rank them in order of significance. Leisure work and travel were included in the list of choices, but the 'home' was not an option so that exposure from members of the family including spouse or partner could be assessed. Figure 31 shows the distribution of these assessments. The fourth choice is excluded from the graphs because the majority of subjects failed to provide a fourth choice.

A. Primary source

More than 40% of subjects chose leisure followed by work (27%) spouse or partner (10%) or friends (6%) as their primary sources. Less than 1% claimed no exposure or 'none'. Other members of the family (excluding spouse or partner) amounted to less than 7%. Own smoking was chosen by less than 1% with travel at about 3% (see Figure 31B). So the ranking for primary sources of exposure to ETS was assessed to be:

LEISURE > WORK > SPOUSE OR PARTNER > OTHER MEMBERS OF THE FAMILY > FRIENDS

B. Secondary source

Leisure was again chosen by more than 25% of subjects as their second source of overall exposure. The distribution pattern is for second sources, however, more spread out. Work, other people and friends were all between 11 and 13%. The ranking was assessed to be:

LEISURE > OTHER MEMBERS OF THE FAMILY > FRIENDS > WORK

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C. Third source

In this case, more than 50% of subjects replied 'none' or provided no answer for their third choice, followed by other people (~ 13%) with friends, leisure and work all between 5 and 9%. Spouse or partner was chosen by less than 2% with the remaining members of the family rated as ~ 8%.

Direct measurements for all these categories was not attempted in this study. Subjectively the study indicated that most people believe their primary exposure occurs firstly at leisure then at work. One in ten claim their primary source is from their spouse or partner. Similarly most subjects did not rate their exposure from other members of the family as significant contributions to their total ETS exposure. Travel was not considered as a major source of exposure.

Figure 32 shows the assessments made by all subjects (48) who claimed their spouse or partner were smokers. From these graphs nearly 50% claim their primary source of exposure was not their spouse or partner.

Figure 33 shows the assessments made by all subjects (133) who claimed their spouse or partner were non-smokers. These distribution graphs show leisure followed by work as their primary source of ETS exposure. These graphs are near identical to the overall assessment of Principal Source of ETS exposure Figure 31.

4.12.3 Pre and post cotinine levels

When pre and post cotinine values for this study are plotted against each other (See Figure 34) R-square = 0.31 suggesting limited correlation. This could be due to differences in the previous 24 hours from the monitoring period relating to time of exposure. Part of the explanation could also be the inadequate limit of quantification of the method of analysis at the low levels found on this study.

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

4.12.4 3-Ethenylpyridine

It was not an objective of this study to compare the levels of 3-ethenylpyridine with those of other direct measurements. However, it was possible to analyse for 3-ethenylpyridine during the nicotine assay.

Figures 35A and B show a plot of 3-ethenylpyridine against SPM and nicotine using logarithmic and linear scales respectively with best fit straight lines for each case. The R-square values for SPM = 0.61 and nicotine = 0.72.

This correlation with nicotine can be regarded as reasonably good and the 'best' correlation of all the measurements compared on this study.

There are a significant number of cases where values were obtained for nicotine where corresponding 3-ethenylpyridine values are belbw the limit of determination.

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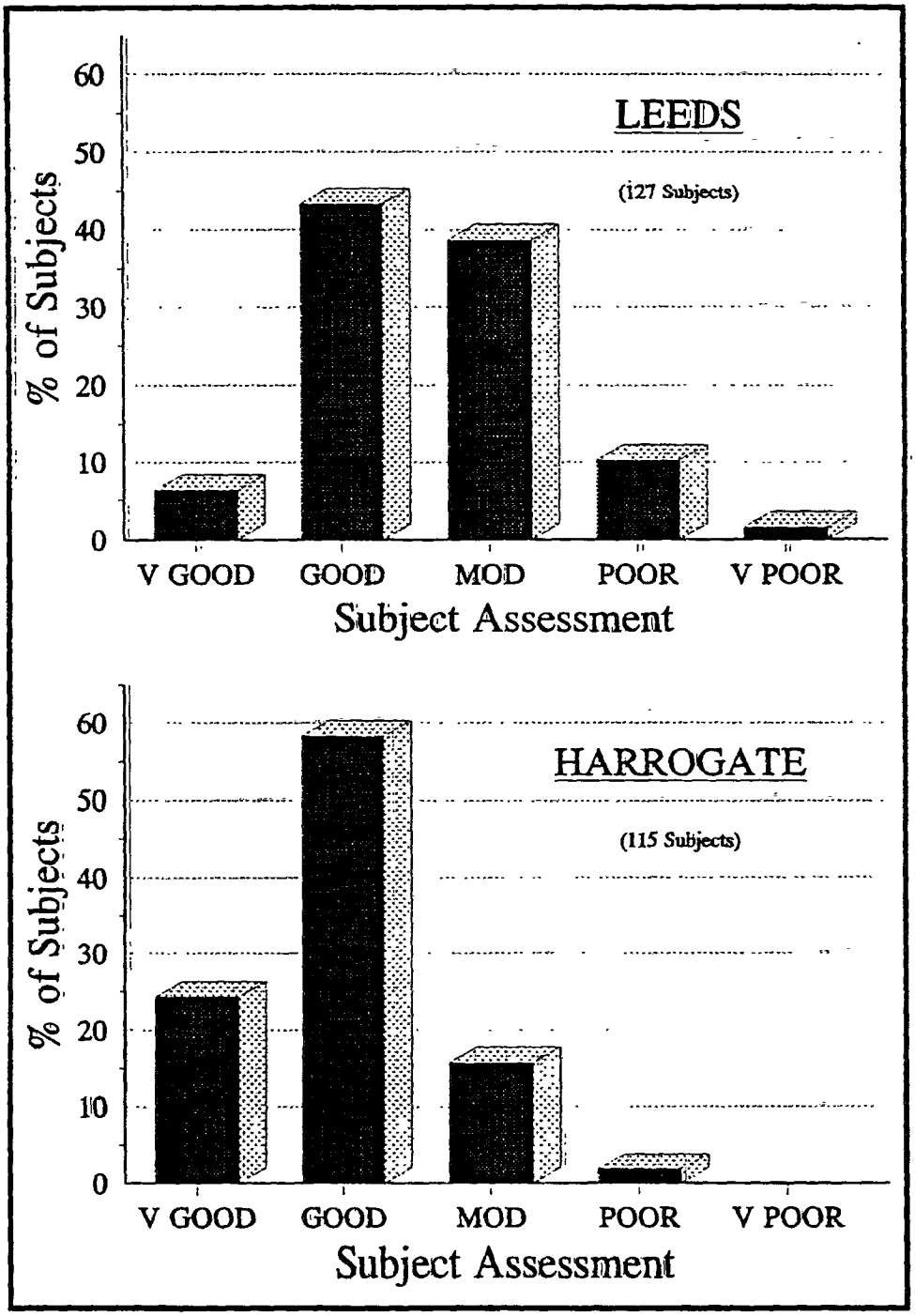
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 29

SUBJECTIVE ASSESSMENT OF GENERAL AIR QUALITY

LEEDS vs HARROGATE



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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 30

SUMMARY OF THE RANGE OF PAS AND SPM LEVELS FOR HARROGATE AND LEEDS

		Harrogate	Leeds
	Number	115	127
PAS ($\mu g/m^3$)	Minimum	20	29
	Maximum	995	1219
	Mean	157	203
	Median	123	164
SPM ($\mu g/m^3$)	Minimum	2	2
	Maximum	98	159
	Mean	8	17
	Median	2	2
% SPM of PAS	Minimum	0.2	0.4
	Maximum	49.2	60.0
	Mean	5.5	8.5
	Median	2.6	2.5

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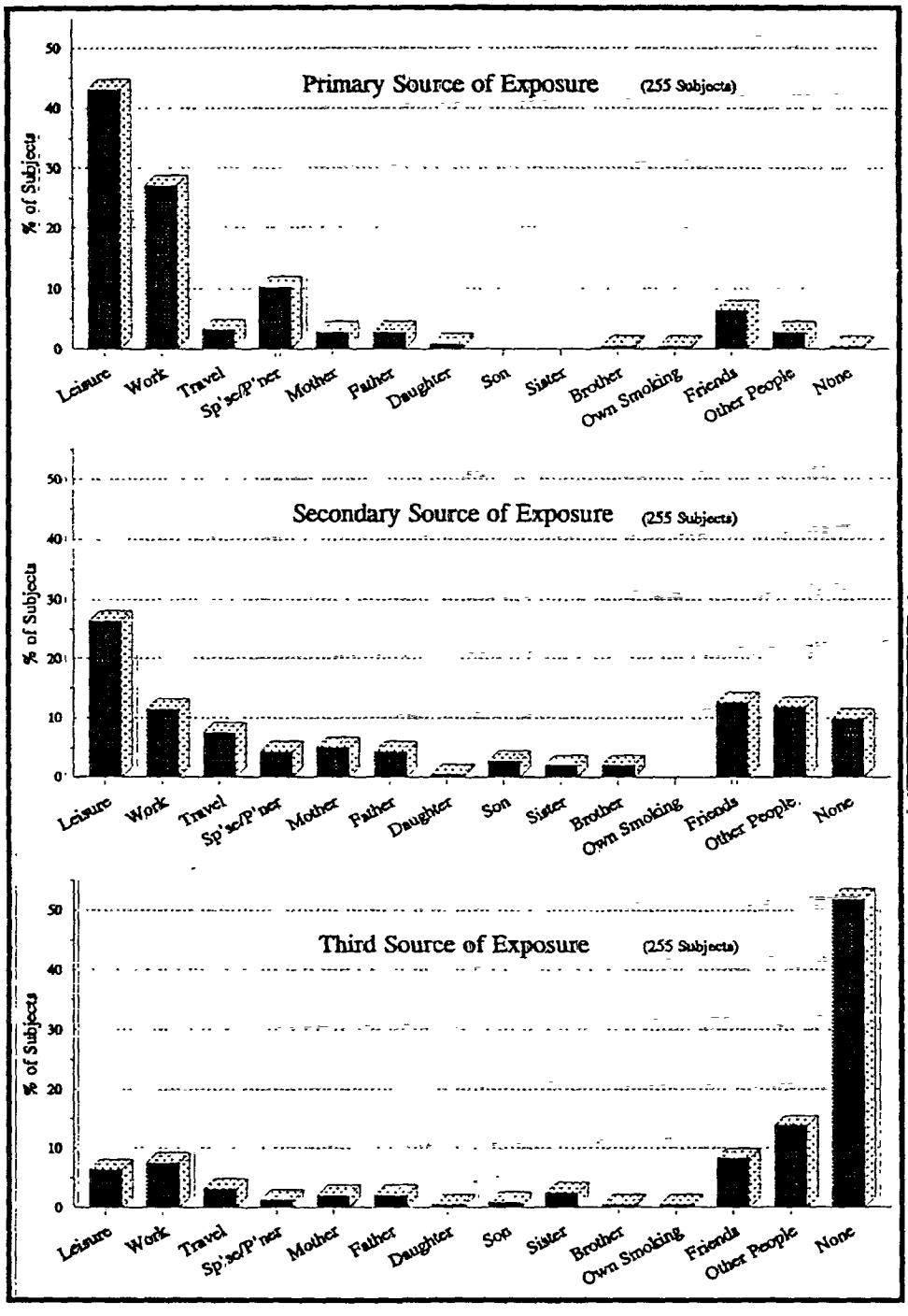
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 31A

SUBJECTIVE ASSESSMENT OF PRINCIPAL SOURCES OF OVERALL ETS EXPOSURE



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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 31B

SUBJECTIVE ASSESSMENT OF PRINCIPAL SOURCES OF OVERALL EXPOSURE

Description	Number (%) subjects					
	Primary		Secondary		Third	
Work	69	(27.1)	29	(11.4)	19	(7.5)
Travel	8	(3.1)	19	(7.5)	8	(3.1)
Leisure	110	(43.1)	67	(26.3)	16	(6.3)
Spouse/partner	26	(10.2)	11	(4.3)	5	(2.0)
Father	7	(2.7)	11	(4.3)	5	(2.0)
Mother	7	(2.7)	13	(5.1)	5	(2.0)
Son	-	-	7	(2.7)	2	(0.8)
Daughter	2	(0.8)	1	(0.4)	1	(0.4)
Brother	1	(0.4)	5	(2.0)	1	(0.4)
Sister	-	-	5	(2.0)	6	(2.4)
Friends	16	(6.3)	32	(12.5)	21	(8.2)
Other people	7	(2.7)	30	(11.8)	35	(13.7)
Own smoking	1	(0.4)	-	-	1	(0.4)
None	1	(0.4)	4	(1.6)	18	(7.1)
No data	-	-	21	(8.2)	114	(44.7)
TOTALS	255		255		255	

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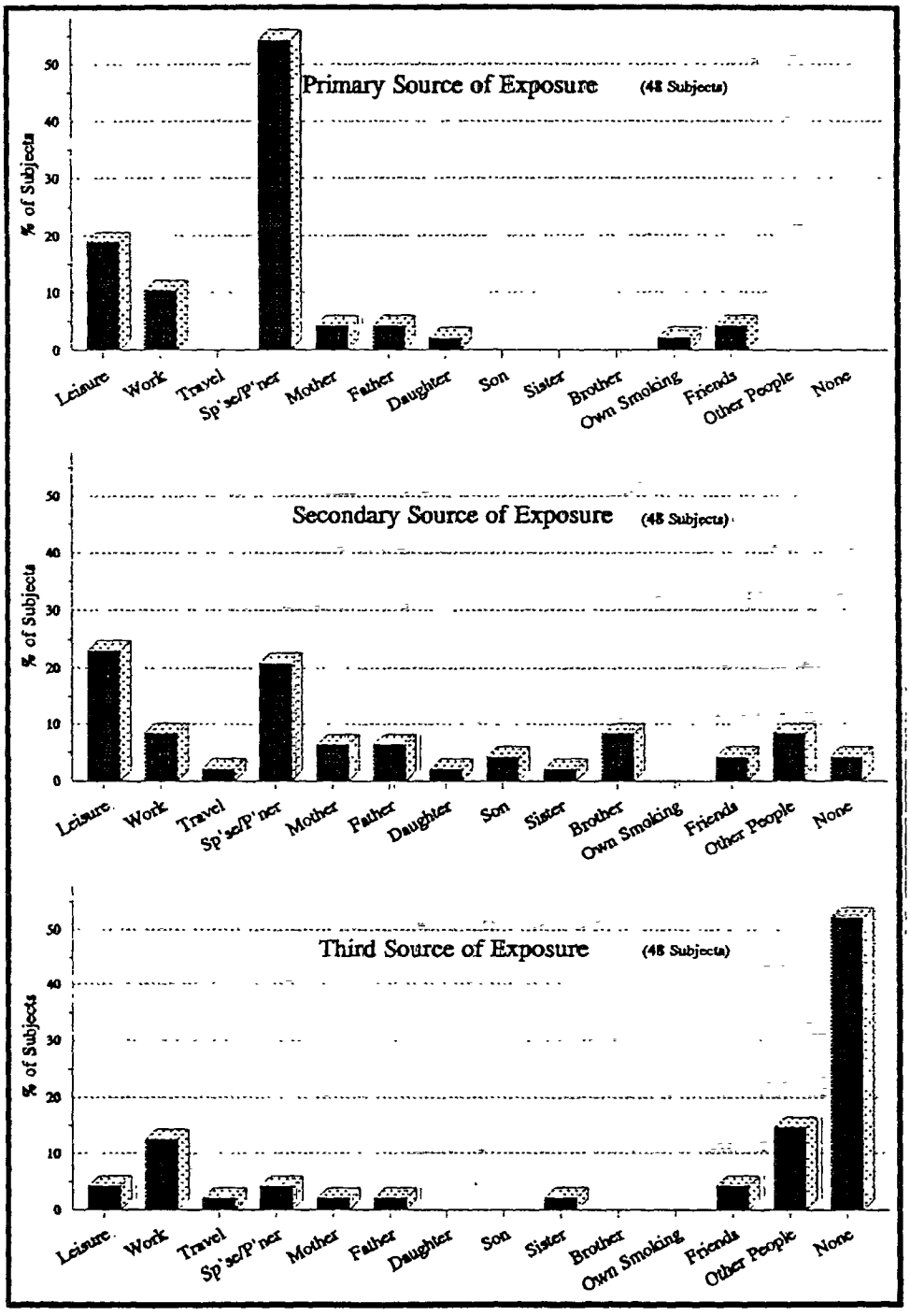
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 32

ASSESSMENT OF PRINCIPAL SOURCES OF OVERALL ETS EXPOSURE (SUBJECTS MARRIED TO SMOKERS)



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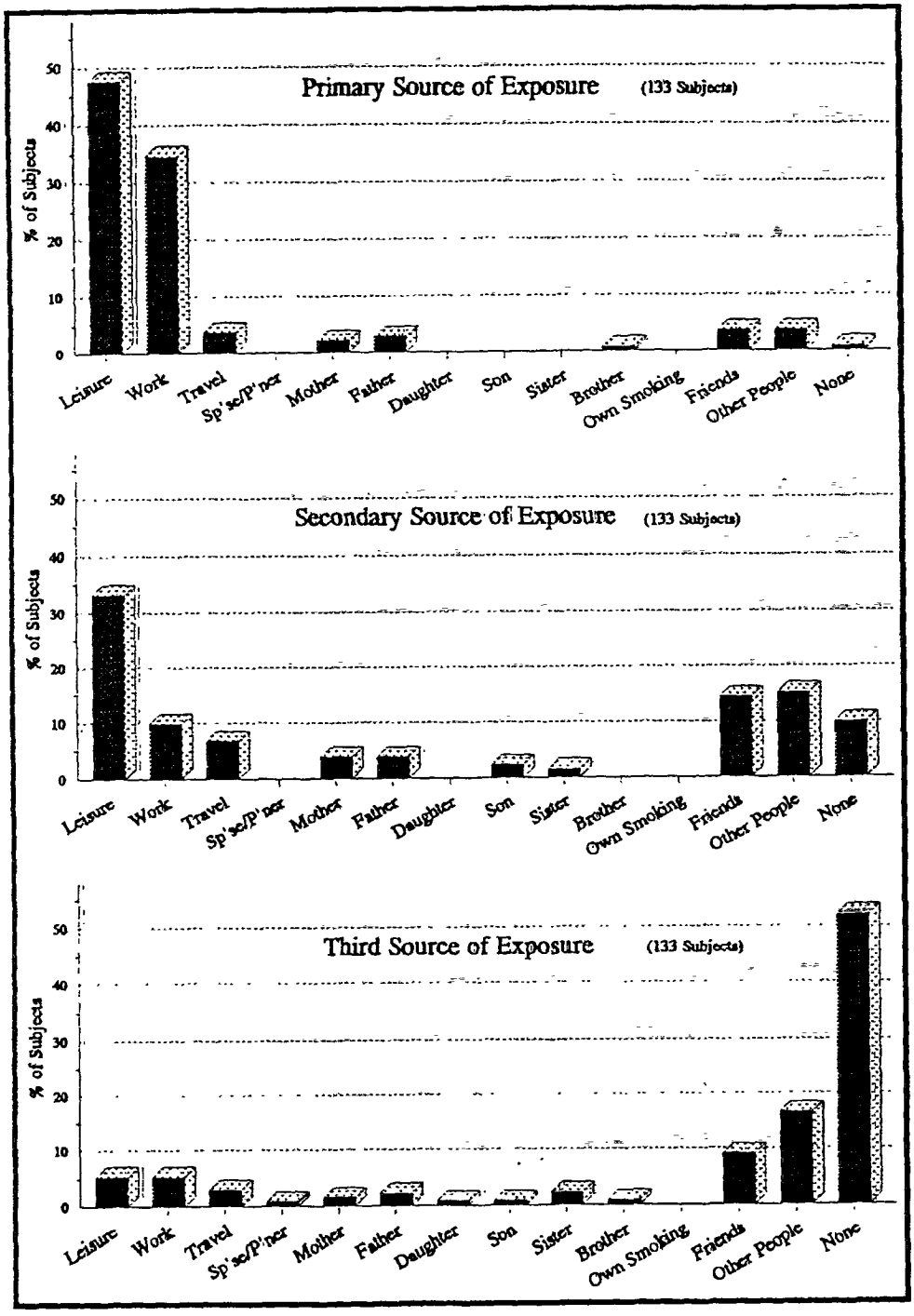
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 33

ASSESSMENT OF PRINCIPAL SOURCES OF OVERALL ETS EXPOSURE (SUBJECTS MARRIED TO NON-SMOKERS)



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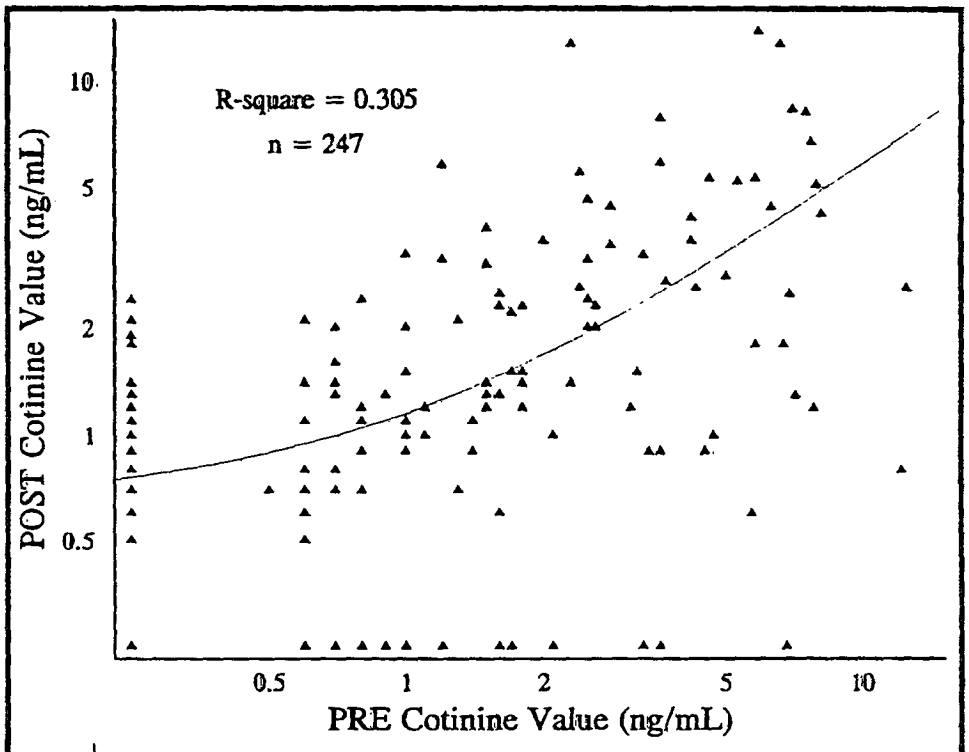
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

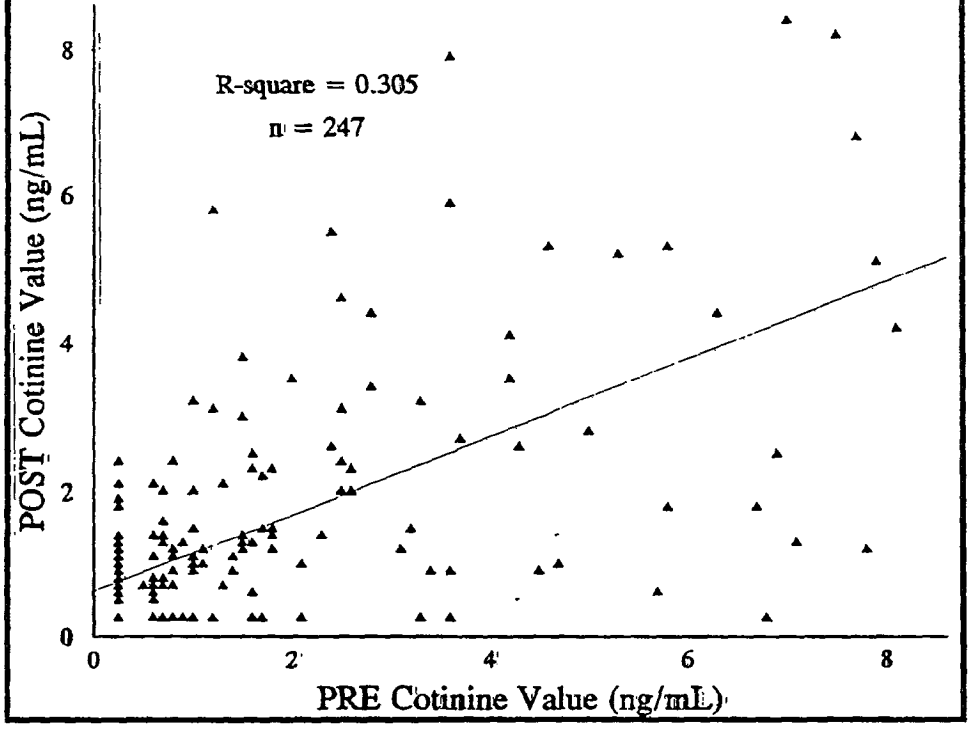
FIGURE 34

CORRELATION OF "PRE" AND "POST" COTININE RESULTS

Logarithmic plot



Linear plot



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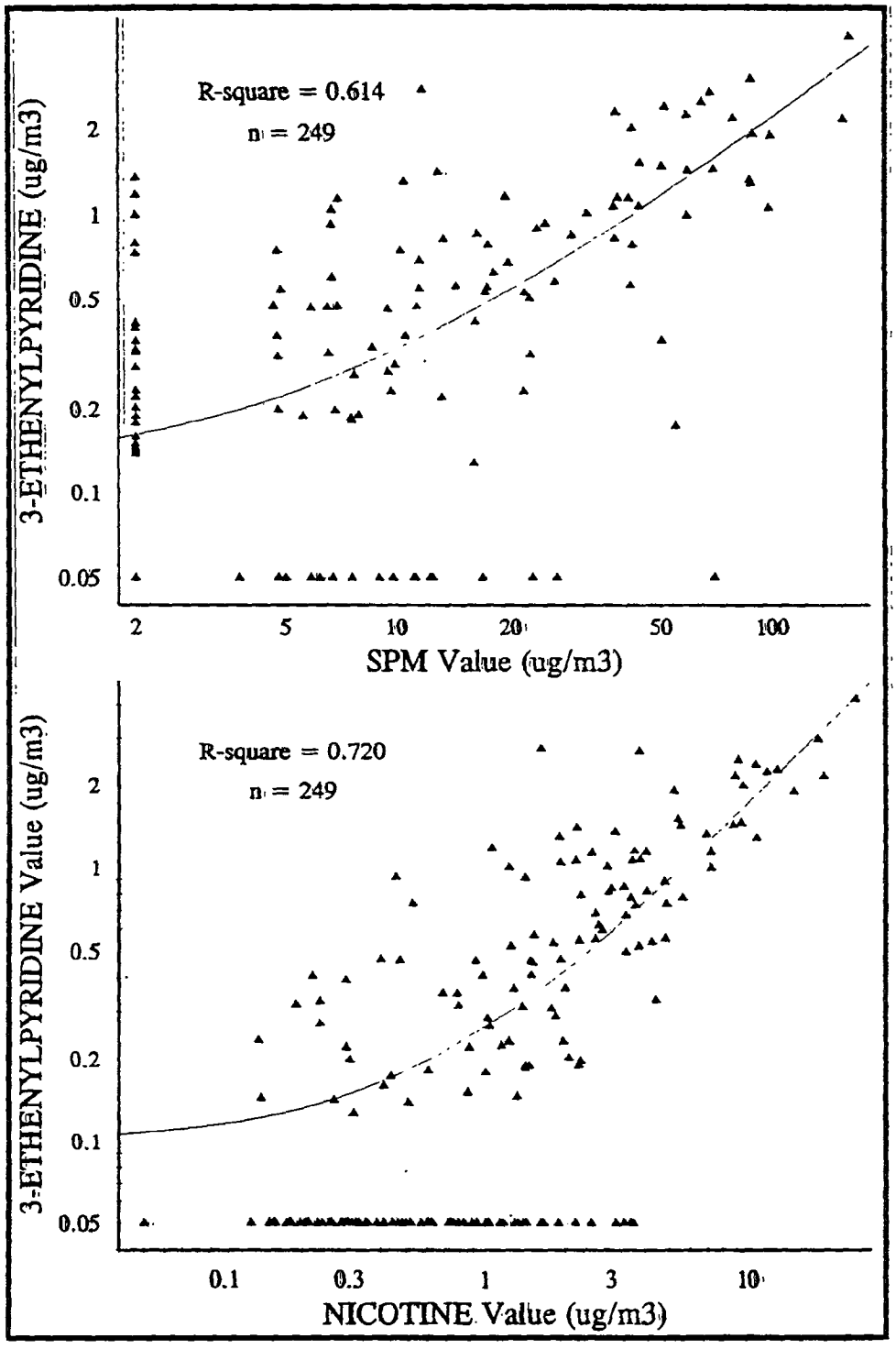
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 35A

CORRELATION OF 3-ETH RESULTS WITH SPM and NICOTINE



Logarithmic plot

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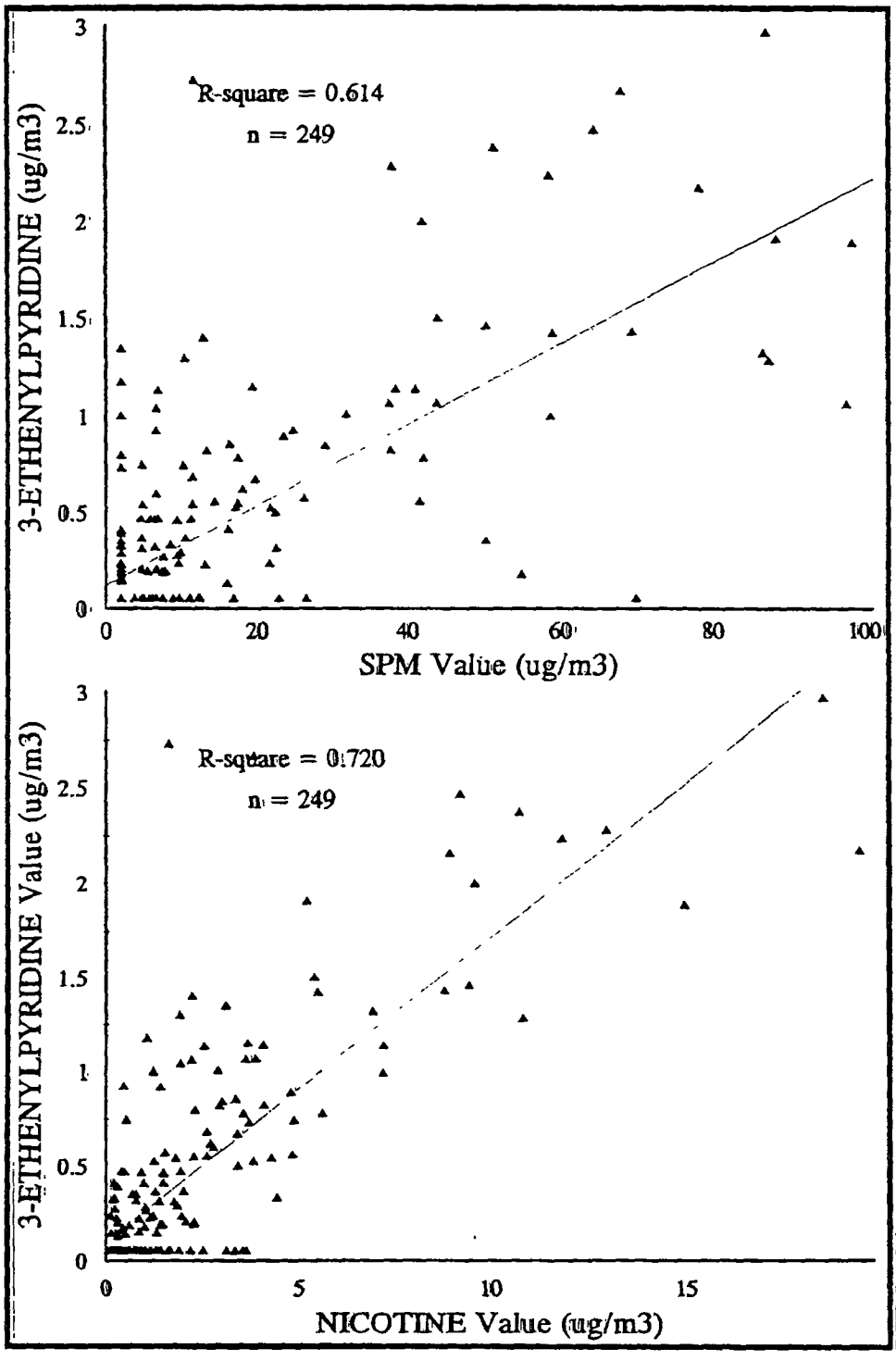
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FIGURE 35B

CORRELATION OF 3-ETH RESULTS WITH SPM and NICOTINE



Linear plot

2023686390

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

4.13 References

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Environment International Vol 17 287-297 (1991).

McNeil A D et al (1987): Saliva Cotinine as an Indicator of Cigarette Smoking in Adolescents.
British Journal of Addiction 82, 1355-60 (1987).

Lee P N (1987): Lung Cancer and Passive Smoking: Association an Artefact due to Misclassification of Smoking Habits?
Toxicology Letters 35, 157 - 162 (1987).

Lee P N (1988): Misclassification of Smoking Habits and Passive Smoking.
Springer-Verlag Berlin (1988).

Guerin M R et al (1992): The Chemistry of Environmental Tobacco Smoke: Composition and Measurement.
Lewis Publishers Michigan USA.

Nelson PR et al (1992): Effect of Ventilation and Sampling Time on Environmental Tobacco Smoke Component Ratios.
Environmental Science and Technology Vol 26 No 10 (1992).

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

5. ARCHIVE

All primary data, or copies thereof, specimens and all equipment on loan from the Study Sponsor will be sent to the Study Sponsor within three months of the date of submission of the final report.

Primary data will be taken to include laboratory data sheets, records, memoranda if appropriate, photographs, computer records that are the result of the original observations and activities of the study and are necessary for the reconstruction and evaluation of the report of the study.

Included will be the questionnaires and diaries completed on behalf of all the subjects selected and used on this study.

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

6. APPENDICES

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

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APPENDIX 1

APPLICATION TO THE CENTRE FOR INDOOR AIR RESEARCH

2023686394

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TITLE:	**Determination of personal exposures to Environmental Tobacco Smoke in British non-smokers**
PRINCIPAL INVESTIGATOR:	**K Phillips**
KEY INVESTIGATORS:	**T Houseman** **D Howard** **J Freeman** **K Tennant** **J Moore** **G Bridger**
INSTITUTION:	**Hazleton UK**

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

RESEARCH ABSTRACT

Title of Project: Determination of personal exposures to Environmental Tobacco Smoke in British non-smokers.

Investigator(s): K Phillips, J Freeman and T H Houseman

Institution: Hazleton UK

ABSTRACT: In the space below, please provide a descriptive summary of your proposed research project.

We propose to investigate typical personal exposures of British non-smokers to Environmental Tobacco Smoke, ETS, through a variety of inter-related measures. There are two main reasons for this investigation. The first is that, although considerable data exist quantifying levels of various constituents of ETS in fixed environments, there is relatively little data describing typical total daily exposures. The second is that much of the existing personal exposure data rely on measures of cotinine, a metabolite of nicotine in the body fluids of non-smokers. The accuracy of this measure has been questioned and this study proposes to examine the relationship between levels of cotinine and measures of chemical exposure to several ETS constituents and to questionnaire responses.

The study would randomly select around 300 non-smokers. Each subject would be investigated for exposure to ETS over a 24 hour period. The measures would be a time-activity diary, a post-sampling questionnaire on perceived exposure, salivary cotinine levels (pre- and post-monitoring period) and personal exposures to nicotine and to particulates. The particulate sample would be analysed for ultra-violet, fluorescence and solanesol content as assessments of the contribution of ETS to the total particulates collected. It is anticipated that such a study would prove information useful to the determination of the extent of ETS exposure and to the assessment of best measures of such exposure.

K. Phillips — 12 August 1992

Signature, Principal Investigator — Date

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HUK Study no 12/64

CENTER FOR INDOOR AIR RESEARCH
1099 WINTERSON ROAD SUITE 280 LINTHICUM, MD 21090
(410) 684-3777 FAX (410) 684-3729

APPLICATION FOR RESEARCH CONTRACT

1. PRINCIPAL INVESTIGATOR. NAME, TITLE, TELEPHONE # AND MAILING ADDRESS.

Tel: 44 423 500011
Fax: 44 423 569565

(A) NAME: Mr Keith Phillips
(B) TITLE: Manager
(C) TELEPHONE #/ FAX #:
(D) DEPARTMENT: Analytical Chemistry
(E) INSTITUTION: Hazleton UK
(F) MAILING ADDRESS: Otley Road, Harrogate
(G) STATE/ZIP: North Yorkshire HG3 1P

2. PROJECT TITLE: Determination of personal exposures to Environmental Tobacco Smoke in British non-smokers

3. KEY WORDS. PLEASE PROVIDE THREE (3) KEY WORDS WHICH WILL BE USED AS REFERENCE HEADINGS.
Environmental
Tobacco Smoke

4. INSTITUTION: NAME AND ADDRESS OF INSTITUTION RESPONSIBLE AND ACCOUNTABLE FOR DISPOSITION OF FUNDS AWARDED ON THE BASIS OF THIS APPLICATION.

(A) INSTITUTION: Hazleton UK
(B) STREET ADDRESS: Otley Road
(C) CITY: Harrogate
(D) STATE/ZIP: North Yorkshire HG3 1PY

5. LOCATION. LIST LOCATION WHERE RESEARCH WILL BE CONDUCTED *IF OTHER THAN INSTITUTION IDENTIFIED IN #4 ABOVE.*

(A)

(B)

6. INCLUSIVE DATES AND TOTAL COSTS OF THIS SPECIFIC PROJECT RELATED TO EACH 12 MONTH PERIOD IF MORE THAN ONE YEAR IS REQUIRED TO COMPLETE PROJECT. SUMMARIZE FROM BUDGET PAGE, ITEM 12(I). IT MUST BE UNDERSTOOD THAT AWARDS FOR 2ND AND 3RD PERIODS ARE DEPENDENT ON CENTER APPROVAL OF CONTINUATION APPLICATION.

	Inclusive Date			Total Cost
(A) 1ST 12 MONTH PERIOD	September 1992	THRU	August 1993	125,000-00 POUNDS STERLING
(B) 2ND 12 MONTH PERIOD IF REQUIRED	-	THRU	-	$
(C) 3RD 12 MONTH PERIOD IF REQUIRED		THRU		$

7. INSTITUTIONAL OFFICER. NAME, TITLE AND TELEPHONE NUMBER OF INDIVIDUAL AUTHORIZED TO SIGN FOR THE INSTITUTION IDENTIFIED IN #4 ABOVE. IT IS UNDERSTOOD THAT THE OFFICER, IN APPLYING FOR A CONTRACT, HAS READ AND FOUND ACCEPTABLE THE CENTER'S MANAGEMENT OF RESEARCH CONTRACTS AND CONTRACT ADMINISTRATION POLICY (other than the payment schedule)*

(A) NAME: Mr M Wilson
(B) TITLE: Contracts Administrator
(C) TELEPHONE: 44 423 500011
(D) SIGNATURE OF INSTITUTIONAL OFFICER: M. Wilson
(E) DATE: 7 September 1992

10 X PRELIMINARY STUDIES* Page 8
(A) FEASIBILITY OF PROPOSED RESEARCH
(B) QUALIFICATIONS OF INVESTIGATOR

8. AIMS - Page 5

11 X EXPERIMENTAL PLAN* Page 9
(A) DESIGN
(B) METHODS
(C) ANALYSIS OF DATA
(D) INTERPRETATION OF RESULTS
(E) TIMETABLE FOR THE INVESTIGATION
(F) LITERATURE CITED

9. SIGNIFICANCE OF PROPOSED WORK - Page 6
(a) Background
(b) Literature
(c) Identification of gaps in proposed research area
(d) Project importance

12 X AVAILABLE FACILITIES AND RESOURCES. Page 13

XXXXXXXXXXXXXX

* APPEND AS MUCH MATERIAL AS REQUIRED. TYPE, SINGLE SPACE, USE 8-1/2" X 11" WHITE PAPER AND LABEL EACH SHEET WITH NAME OF THE PRINCIPAL INVESTIGATOR IN THE UPPER RIGHT HAND CORNER AND PAGE NUMBER AT THE BOTTOM. CONSECUTIVELY NUMBER EACH ADDENDUM BEGINNING WITH PAGE 5. DO NOT INSERT PAGES BETWEEN PAGES 1 AND 6, E.G., 2A, 2B, 3A, ETC. INCLUDE NINE COPIES AND AN ORIGINAL. IF SENDING PHOTOGRAPHS, INCLUDE 2 ORIGINAL SETS. NOTE: EACH OF THE NINE COPIES MUST BE PLACED IN A BINDER PER MAILING INSTRUCTIONS.

* Please see preferred method of payment on Hazleton Quotation.

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

12.BUDGET. Detailed specific needs for the first 12-month period. Estimate category sub-totals for 2nd and 3rd periods, if required. Append justifications.

(a) Salaries. List personnel by name and title. Indicate individuals % time to be spent on this project.	$ 1st period	$ 2nd period	$ 3rd period
% Professional:			
% Technical:			
% Other:			
Fringe benefits payable at institution's rate of %			
Category (a) Sub-Total			
(b) Consultants (per diem, travel & expenses):			
Category (b) Sub-Total			
(c) Supplies & Expense: Consumables (by category)			
Animals and related costs			
Other expenses (itemize)			
Category (c) Sub-Total			
(d) Travel Expenses:			
Category (d) Sub-Total			
(e) Alterations and Renovations			
Category (e) Sub-Total			
(f) Sub-contracts			
Category (f) Sub-Total			
(g) Equipment			
Category (g) Sub-Total			
(h) TOTAL DIRECT COSTS			
(i) Indirect costs not to exceed 25% of the sum of (a) thru (f):			
(j) TOTAL PROJECT COSTS			

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13. **BUDGET**

	Pounds Sterling
Pilot Study (10 volunteers)	7,500
Main Study (minimum of 280 volunteers)	
• Volunteer recruitment, administration, reimbursement	24,500
• Collection/delivery of kits; equipment maintenance	9,500
• Analytical phase, to include method development/ validation and routine analysis of samples for total particulates, nicotine, UVPM/FPM, solanesol and salivary cotinine	75,000
• Prepare a report and a manuscript for publication	8,000
TOTAL	**125,000**

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14 IX BIOGRAPHICAL SKETCH of all professional personnel listed in 12(a). Append. Please include the following: Name, title, education, scientific field, major research interest, research and/or professional experience and publications. (Limit list of publications to the 20 most important and/or relevant.)

See Appendix C

15 IX a) Are HUMAN SUBJECTS to be used in this research? _____ Yes _____ No
If yes, attach Institutional Review Board approval for procedures involving human subjects.

See Appendix D

b) Are LABORATORY ANIMALS to be used in this research? _____ Yes _____ No
If yes, attach Institutional Animal Care and Use Committee approval for procedures involving animals

Not applicable

16 IX SIGNATURE OF PRINCIPAL INVESTIGATOR: It is understood that the applicant in applying for a Contract has read and found acceptable the Statements of Policy and Terms Under Which Project Contracts Are Made appearing in the application package. **(other than payment schedule)**

K. Phillips 12 August 1992

Signature of Principal Investigator Date

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8. AIMS

The broad objective of the proposed work is to determine, through a variety of inter-related measures, the extent of exposure to ETS in typical British non-smokers.

The specific aims of the project are as follows:

1. To determine, in non-smoking British volunteers, the range and median levels of 24 hour exposure to nicotine and to ETS-related particulates.

2. To assess the contribution of exposure to ETS from different environments such as homes, the workplace and leisure and travel situations.

3. To assess whether non-smokers who are married to smokers have significantly higher exposures to ETS than non-smokers married to non-smokers.

4. To evaluate the extent of correlation between the different methods of exposure determination; questionnaires, salivary cotinine measures and personal monitoring of exposures to airborne constituents.

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9. SIGNIFICANCE OF PROPOSED WORK

a) Background

Two approaches have been used to assess whether there is any risk associated with exposure to ETS. One is based on epidemiology and the other based on the quantities of smoke constituents to which non-smokers are exposed. Further information is required on typical exposure levels in order to address questions relating to epidemiology studies and to obtain a better assessment of how much ETS people are exposed to.

Most of the information about the exposure of non-smokers to ETS is based on measurements of ETS levels in locations such as homes, offices and restaurants with assumptions about the time spent in these locations. There have been several such studies, particularly in the USA, but not enough to characterise properly the range of ETS exposure of non-smokers. It is, therefore, important to obtain further information for a variety of other situations, including different countries with various climates and lifestyles.

Surprisingly, there have, until recently, been few attempts to measure exposure of people directly as they go about their normal lives, moving from location to location, even though this approach should provide more realistic results than those calculated from ETS levels in various locations. Although this personal monitoring technique has been common practice in the industrial hygiene field for several years, it is only recently that the analytical methodology has been refined sufficiently to allow ETS measurements to be carried out by this approach. A few ETS exposure studies of this type have now been completed or are underway.

Nevertheless, further studies in a variety of countries are still required in order to obtain sufficient information with which to address some of the important ETS issues.

Although levels of both nicotine and ETS particles have been determined in several studies of locations, personal monitoring studies have tended to measure nicotine but not particles. In view of the limitations of nicotine as a marker for ETS and the importance often attached to particles, there clearly is a need for complementary personal monitoring studies in which ETS particles are also measured, especially now that the UVPM (ie. ETS particulate matter measured by ultra-violet light), FPM (ie. ETS particulate matter measured by fluorescence) and solanesol methods are available for estimating the ETS contribution to total particles.

A criticism of existing epidemiological studies of ETS is that they failed to include a direct measure of exposure level. Spousal smoking has frequently been used as an index of exposure in these studies but the validity of this approach is open to question. It is, therefore, important to determine whether reported extent of spousal smoking correlates with directly measured exposure. For the same reasons, it would be useful to determine how well directly measured ETS exposure can be predicted by questionnaire or by measurements of salivary cotinine since these approaches are also used as an alternative to direct measurements. It would also be useful to establish how peoples' personal assessment of their exposure compares with their measured exposure.

Smoking bans are being introduced in the workplace and in various public leisure and travel situations. It would be helpful to obtain further information on the extent of exposure in these situations to assess how each contributes to overall exposure.

The Study proposed here will help to address these issues.

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

b) Literature

Perhaps the most extensive published evaluation of data related to ETS exposure is the monograph recently published by Guerin et al (Guerin, Jenkins and Tomkins, The Chemistry of Environmental Tobacco Smoke: Composition and Measurement, Lewis Publishers Inc. 1992). In this review of the existing literature, fourteen field studies of nicotine levels and twenty three field studies of particulate levels were tabled. Only one these studies referred to data acquired in the United Kingdom and so there is little to base comparisons in the literature between the predominately US based literature and a United Kingdom situation.

The same monograph briefly discusses the literature related to personal monitoring and biomarker assays. One personal monitoring study (Proctor et all, Environmental International 17, 287-297) measured personal exposures to nicotine and measured salivary cotinine levels in non-smoking British women. This study suggested a lack of correlation between cotinine and nicotine exposure levels. However, the study was small (50 subjects) and made no assessment of particulate exposures. US data on particulates (Spengler et al, Environmental Science and Technology, 19, 700-706, 1985) reported that 24 hour exposures to particulates were around 40 ug/m3 higher in those living in smokers' homes compared to non-smokers homes'. However, these researchers used comparative location techniques rather than chemical apportionation to determine the ETS contribution to particulates.

c) Identification of gaps in proposed research area

Our proposal addresses several gaps in the literature pertaining to the issue of population exposure to ETS. These are:

1. The sparsity of data specific to the United Kingdom. As far as we are aware there is only one UK based published study that has attempted to resolve the issues addressed in our proposal. Because of this it is uncertain whether the larger US database can be applied to the UK.

2. Little or no data exist on particulate exposure directly related to ETS as measured by chemical apportionation techniques.

3. The comparison of exposure assessment techniques (questionnaires versus chemical monitoring versus biomarker measurements) has rarely been addressed in studies measuring more that two of these comparative measures. The proposed study would compare six different measures (questionnaire, nicotine exposure, UV-PM exposure, Fluorescence-PM exposure, solanesol and salivary cotinine).

d) Project importance

Several agencies are currently considering the potential effects of exposure to ETS. In the United Kingdom, the Independent Scientific Committee on Smoking and Health stated it its Fourth report published in 1988 that it is recognised that the whole area of investigation of the composition and concentration of ETS is a difficult one and that it would keep the issue under review as new research findings became available. UK specific data would presumably be of value to this committee. On a broader basis, the investigation should prove useful in terms of an example of the use of personal monitoring techniques for investigating exposures to substances found in the environment.

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

10 PRELIMINARY STUDIES

a) Feasibility of the proposed research

A novel active monitoring device, which allows the simultaneous collection of airborne nicotine and particulates has been devised for this experiment. The effectiveness of this device has been evaluated in controlled experiments and we are confident that the collection technique will appropriately represent the personal exposures. The design and function of this device is described fully in the experimental plan. Apart from this, all of the methods proposed are standard and appear in the peer-reviewed literature.

b) Qualifications of investigator

The curriculum vitae of all the key investigators are appended to this proposal. The Institution, Hazleton UK, is experienced both in subject interview techniques and in the analysis if environmental and biological samples.

A profile of the company is attached to this proposal.

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

11 EXPERIMENTAL PLAN

a) Design

The following is a brief description of the study design. 300 non smokers will be randomly selected from an existing database of 11,000 subjects held by GHBA/Hazleton Clinics in Leeds UK.

Either five or six volunteers will be studied each day such that eleven subjects will be studied every two days, including weekends. Each volunteer will be monitored for a continuous period of 24 hours.

The volunteers will all be from Yorkshire in the North of England, and will be selected to be representative in terms of age, sex and locality (urban/rural).

Their exposure to nicotine, TSP, UV-PM (particulates measured by UV light) F-PM (particulates measured by fluorescence) and solanesol will all be monitored.

At the beginning and the end of the monitoring period, saliva samples will be taken. The volunteers will maintain a diary throughout the monitoring period. A questionnaire will be completed at the end of the 24 hour period.

Prior to the start of the main study (approximately 3 to 4 weeks) a "pilot study" or trial will be conducted using ten volunteers. The purpose of the trial is to assess all aspects of the main study including collection, analysis and questionnaire completion and to highlight any problems that might occur in the main study.

b) Methods

i) Subjects

300 non-smokers will be randomly selected from an existing database of 11,000 subjects held by GHBA/Hazleton Clinics in Leeds, UK. All volunteers are to be non-smokers aged between 20 and 60 years of age. Subjects will reside in the Leeds and Harrogate area in the North of England and they will be distributed based on age, sex and locality (urban/rural).

A pre-acceptance questionnaire will be used to select an excess of volunteers so that in the event of drop-outs suitable replacement candidates can be selected. The volunteers will be provided a financial incentive for their involvement in the study.

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ii) **Sample delivery and collection**

A minimum of 280 volunteers results are required. To acheive this, five or six subjects will be monitored daily producing 11 samples every two days over a period of fourteen consecutive days. Thus 70 results will be obtained in a two week period. This regime will be repeated on three consecutive occasions.

The personal monitors will be delivered to the volunteers at pre-determined locations and times and will be collected as close as possible to 24 hours later. The monitor pump will be turned on and off by the investigators and not by the subjects. Times of start and finish, as well as recorded cycles of the pumps, will be recorded.

Saliva samples will be taken from each subject at the beginning and at the end of the 24 hour sampling period.

Questionnaires will be completed by the investigator who will ask a series of pre-determined questions, coded for later analysis. These questions will be asked at the end of the sampling period. The volunteers will also carry a time-activity diary in order to record observations throughout the monitoring period.

iii) **Collection and analysis of airborne nicotine and particulates**

The collection of these analytes relies upon the use of a compact collection system which is worn by the subject in order to sample the air to which he/she is exposed. It consists of two filters in series connected to a sampling pump. The first filter collects the total particulates and the second, which is acid-treated, traps nicotine vapour.

Air is drawn through the filters by a small, quiet, battery powered pump which is concealed in a small bag worn at the subject's waist level. The pump is set at a flow rate of 139 ml/min so that a total volume of 200 litres is drawn through the pump during the 24 hour monitoring period.

The filter holder is attached to a rigid wire "necklace" which holds the monitor in place and allows ease of removal. A clip will be provided as an alternative to the necklace.

During periods of sleep or bathing the monitor will be taken off but be placed close to the subject. Such events will be noted in the time-activity diary.

In brief, the analytical methods to be used are as follows:

The analysis of the nicotine and 3-Ethenylpyridine contained on the acid treated filter involves extraction into dis-isopropyl ether (DIPE) (containing 0.1m/l triethylamine and 2.0 mg/l N-ethylnornicotine (internal standard) from sodium hydroxide which is used to basify the filter.

The DIPE extract is then analysed by capillary gas chromatography with nitrogen specific detection.

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PHILLIPS

The total suspended particulate concentration is determined gravimetrically by the difference in weights of the front teflon pad before and after sampling.

After weighing, the pad is extracted in methanol in order to determine UV-PM, F-PM, solanesol and any residual nicotine and 3-Ethenylpyridine that might have been trapped on the front filter.

iv) Collection and analysis of saliva

Saliva will be collected from each subject immediately before and after each monitoring period. This will be achieved by the subject chewing on a dental swab for around a minute. The swab is then returned to the laboratory sealed in its salivette container.

The saliva is recovered by high speed centrifuge for two minutes. Cotinine and N-ethylnorcotinine (internal standard) are extracted from the saliva and the extract analysed by GC with mass selective detection.

v) Detection limits

Under the sampling regime described, the detection limits for the various analytes are expected to be as follows:

Total particulates	20 $\mu g/m^3$ as ETS particulates
UV-PM	5 $\mu g/m^3$ as ETS particulates
F-PM	5 $\mu g/m^3$ as ETS particulates
Solanesol	10 $\mu g/m^3$ as ETS particulates
Nicotine	0.5 $\mu g/m^3$
3-Ethenylpyridine	0.5 $\mu g/m^3$
Salivary cotinine	0.5 $\mu g/ml$

vi) Quality Control

The study will be performed where appropriate in accordance with the Good Laboratory Practice provided as guidelines of the UK Department of Health compliance programme (1989). Where appropriate all work will be performed under Hazleton's standard operating procedures.

Any deviations from the protocol will be recorded as a file note against the raw data and highlighted in the final report.

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c) **Analysis of data**

Subject information and corresponding analytical data will be compiled in a database as the study progresses.

Computation of means and ranges for each of the analytes and correlations between the different analytes will be achieved through standard statistical procedures.

d) **Interpretation of the results**

The results will be reported both as a detailed research findings report to the Center for Indoor Air Research and if the data allow, as a publication for a peer-review scientific Journal.

e) **Timetable of investigation.**

Should approval be received, the pilot phase of the study could begin within one month. Field sampling would occur over a period of around two and one half months. Data analysis and reporting is expected to be complete three months after the completion of sampling.

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

12. AVAILABLE FACILITIES AND RESOURCES

Hazleton UK is the European Headquarters of Hazleton Corporation, a wholly owned subsidiary of Corning Laboratory Services Inc. The company provides a wide range of product development and safety evaluation services to the pharmaceutical, agrochemical and chemical industries.

The laboratories at Harrogate, which occupy 185,000 square feet on a 20 acre site, are engaged in general and reproduction toxicology, molecular toxicology, metabolism and pharmacokinetics and biological and chemical analysis. The 50 bed GHBA/Hazleton Clinic, Leeds, undertakes clinical pharmacology studies in healthy volunteers and a variety of patient population groups.

All studies conducted by Hazleton and GHBA satisfy requirements for Good Laboratory and Good Clinical Practices (GLP and GCP) respectively.

Of the 625 staff, 159 are degree level and 39 doctorate level. Five percent of time is devoted to training, as part of the company's Total Quality Management programme.

The modern analytical laboratories are particularly well equipped to undertake the proposed study and the Principal Investigator has direct experience of tobacco smoke analysis studies.

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

APPENDIX 1.1

CVs FOR KEY INVESTIGATORS

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R: REDACTED MATERIAL

PE11

CURRICULUM VITAE

1. PERSONAL DETAILS

Name: PHILLIPS, Keith

Date of Birth: **REDACTED**

Job Title: Manager, Analytical Chemistry

Education:

1960-1965	'O' Levels in English Language, English Literature, Welsh, French, Geology, Physics, Maths, Chemistry, Special Arithmetic
1965-1967	ONC Denbighshire Technical College Chemistry, Mathematics, General Studies.
1967-1969	HNC Denbighshire Technical College Chemistry, Special in organic Synthesis.
1969-1970	GRIC University of Salford, Manchester (Part I)
1973.	Elected Licentiate of the Royal Society of Chemistry
1982	GRSC (by counselled experience).
1991	Elected Fellow of the Royal Society of Chemistry.

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2. PRESENT EMPLOYMENT

Hazleton UK

1989-Date	Head of Analytical Chemistry Responsible for Residues Chemistry, Physicochemistry, Chemistry Services. The service offered encompasses GC, HPLC, FTIR, GCMS, LCMS for the Agrochemical Industry.
1985-1989	Head of Chemistry Services Responsible for the Instrument Laboratory, Mass Spectrometry facility, and Formulation Analysis comprising of Tobacco, Toxicology Support and Pharmaceutical Analysis. Responsible for scheduling and revenues projection for all sections within Chemistry Operations and provision of PBUs for business development. Also interfacing between operations and BD for present and forecasted workloads.
1983-1985	Head of Chemistry Operations Responsible for all aspects of the administration, organisation and management of Chemistry Operations ie Analytical and Metabolic. This covers the actual performance, both scientific and financial, of all the projects carried out for clients within chemistry and meeting the standards laid down by company policy. The scope includes all the resources, human and physical attached to this area, and demands motivation of all the people involved. Also responsible for ensuring the smooth and efficient day-to-day running of the profit centre by active participation and control and by maintaining a close liaison with the

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Director of Chemistry and the Principal Scientist for Metabolism and Pharmacokinetics in regard to proposal activities and project status.

1978-1983

Head of Central Dispensary
Initially made responsible for setting up the facility and resources to run it. Responsible for the management of all test articles received at Hazleton, in accordance with Good Laboratory Practice (GLP) regulations. The formulation of all the materials using detailed Standard Operating Procedures, training staff, preparation and implementation of career development programmes, competence check lists etc. Also responsible for all financial aspects of the department.

1974-1978

Senior Residues Analyst
Responsible for the development/evaluation and subsequent application of many analytical procedures for measurement of crop protection chemical residues. Project Manager for a series of plant and soil metabolism studies using mainly radiochemical techniques.

3. PAST EMPLOYMENT

1972-1974

Tobacco Research Council Laboratories
Analyst/Synthetic Chemist
Primarily concerned with investigations into the possible effects of tobacco smoking on health.
Responsible for the synthesis of an unsaturated precursor subsequently reduced using tritium gas to give a high specific

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radioactivity material for inclusion in the tobacco. Also involved with the evaluation of 2, 4-D and 2, 4, 5-T as endogenous cigarette smoke markers.

1970-1972

Wellcome Foundation, Berkhamsted
Principal Senior Technician
Responsible for the day to day management of all senior and junior technicians and reported directly to the Head of the Chemotherapy Unit. Actively involved in the synthesis of cyclopropane carboxylic acid derivatives (chrysanthemates) subsequently used for synthesis of pyrethroids. Gained wide experience of Grignard reagents during this period of employment.

1965-1969

Monsanto Chemicals Limited, Ruabon
Trainee technician - Senior Technician
During the first 12 months became acquainted with the handling and use of organic chemicals and received training in basic laboratory techniques.
Final position was as a senior technician reporting directly to a senior chemist. Gained experience in the synthesis of a wide range of anti-ozonant compounds and their subsequent testing using a rheometer for the studies of rubber vulcanisation reactions.

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4. TRAINING COURSES

1971-1972	Interpretation of NMR, UV, IR spectra held at Berkhamsted.
1974	Attended a residential course on radioisotope techniques at the University of Loughborough.
1980	Attended a residential Management Training Course.
1981	Report writing course for chemists.
1982	Management Training Course (1 week residential).
1983/4	Management/Supervisor training course.
1985	Management Course/Time Management.
1986	Report Editors course for Chemists/Scientists.
1987	Total Quality Course.
1988	GLP in the Chemical laboratory RSC - ICI Wilton
1989	Quality Refresher Course.
1989	LIMS for the Chemistry Laboratory RSC London.
1989	Residue levels on crops and their analysis (BCPC London)
1989	PC training (Word Perfect).

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R: REDACTED MATERIAL

1990	COSHH in laboratories.
1990	Management Skills course.
1991	Management Skills course.

5. PROFESSIONAL SOCIETIES.

REDACTED

6. SCIENTIFIC PUBLICATION

Synthesis of High Specific Activity Tritium Labelled Dotriacontane.
Journal of Labelled Compounds and Radiopharmaceuticals
Vol XIV, No 2 1978.

7. OTHER RELEVANT DETAILS

1978	Worked in a problem solving role at the Agrochemical Division of Bayer AG in Leverkusen West Germany in their Pesticide Residues Laboratory. This work in West Germany enabled Hazleton Laboratories to complete a project on behalf of the sponsor and submit a report to the PSPS.
1985	Co-author of Chemistry Division's Career/training programmed in chemistry.
1988	Development of HPLC/GC training course with Leeds Polytechnic. Subsequently modified and 25 chemists trained extensively in chromatography over 1-2 years.
1990	Developed brochure and overhead presentation on COSHH in laboratories for HUK. Presentation made to Health and Safety Executive.

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

R: REDACTED MATERIAL

1990	Member of the HUK COSHH Committee.
1991	Involved with RSC Chemistry at Work Exhibitions involving schools in Yorkshire.

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

R: REDACTED MATERIAL

PEII

CURRICULUM VITAE

1. PERSONAL DETAILS

Name: HOUSEMAN, Terence Henry

Date of Birth: REDACTED

Job Title: European Industry Development Manager

Education:

1961-1965 University of Bradford
1st class Honours Bachelor of Technology Degree in Industrial Chemistry (specialising in high polymer chemistry and chemistry of dye stuffs).

1967-1970 University of London.
PhD thesis entitled "Radiochemical studies of the oxidation of natural rubber"

2. PRESENT EMPLOYMENT

Hazleton UK

1991- European Industry Development Manager

1987-1991 Head of Business Development, Chemical and Medical Sciences.
Responsible for a complete commercial/business support function which embraces and oversees all financial

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	budgeting, planning and business development activities of the division.
1985-1986	Director of Chemical and Medical Sciences Responsible to the Managing Director for all scientific and commercial aspects of the Division, which now incorporates Hazleton's clinical activities.
1980-1985	Director of Chemistry, Responsible to the Managing Director for all aspects of the administration, organisation and management of assigned operating areas, including Analytical Chemistry, Metabolism and Pharmacokinetics and HAZLETON Masspec (and until recently, Central Dispensary). Also responsible for the commercial activity of the Division.
1976-1979	Head of Chemistry and Metabolism Responsible to the Director of Research Operations for all operational and scientific aspects of Analytical Chemistry, metabolism and Pharmacokinetics and Central Dispensary, including establishment of the latter. This also included delegated responsibility for commercial activities such as business development.
1974-1976	Head of Radio and Analytical Chemistry Responsible for establishing and developing the department as a viable profit centre, with responsibility for all operational and scientific aspects and delegated responsibility for business development.

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

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3. PAST EMPLOYMENT

1971-1974	Tobacco Research Council Laboratories Head of Chemistry Research Services (and Radiological Protection Officer) Responsible for providing a chemistry service (analytical and synthetic) to other departments within the company, eg Pharmacology, Biology, and collaborating with external TRC grantees.
1970-1971	Tobacco Research Council Laboratories Radioanalytical Chemist Responsible for studying the smoke transference of exogenous and endogenous tobacco constituents to mainstream and substream smoke with the ultimate objective of determining the fate of constituents in the human smoking situation.
1965-1970	Natural Rubber Producers' Research Association. Radioanalytical Chemist Responsible for studying mechanisms of oxidative mainstream and cross-link scissions in vulcanized and unvulcanized natural rubber. Radioanalytical techniques featured strongly in this work.
1962	Undergraduate Associated Chemical Companies Ltd, Central Research Laboratories Industriall training period
1963	Sandoz Products (Dye Stuffs) Ltd Industrial training period

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

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1964	Undergraduate Natural Rubber Producers' Research Association Industrial training period

TRAINING COURSES

1972	Radiological Protection Course - Harwell
1980-1984	HLE Senior Management residential training course Plus numerous specialist short courses on accountancy, management etc.
1985	Organisation Development - Scott Grant Sales Development - Industrial Training Services Ltd Building an effective team - Industrial Training Services Ltd
1988	Developing Key Marketing Skills - Cranfield School of Management
1989	Good Clinical Practices Workshop - Oxford Workshops
1989	Customer Service Workshop
1991	Customer Action Planning Systems - Corning Inc Management Skills Course - Hazleton Training Unit Senior Management Team Building Workshop - Hazleton Training Unit Presentation Skills - Hazleton Training Unit
1992	Negotiation Skills - Hazleton Training Unit

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

R: REDACTED MATERIAL

3. PROFESSIONAL SOCIETIES

REDACTED REDACTED

5. SCIENTIFIC PUBLICATIONS

Barnard, D, Houseman, T H, Porter, M R and Tidd, B K (1969)
"Thermal racemization and cis, trans - isomerization of allylically unsaturated di - and poly-sulphides: a mechanism involving branched sulphur chains".
Chem. Comm. - 371

Barnard, D and Houseman, T H (November 1969) "The application of radiochemical methods to the study of oxidation of natural rubber". Symposium of Oxidation. Hall of Fame Ceremony, Institute of Polymer Science. Adron University.

Ayrey, G, Barnard, D and Houseman, T H (1971)
"The use of radioisotopically labelled analytical reagents in organic chemistry".
Chem Rev 71 371

Barnard, D, Cain, M E, Cuneen, J I and Houseman, T H (1972)
"Oxidation of vulcanized natural rubber".
Rubber Chem Technol, 45, 381

NB This paper was also presented at a meeting of the Division of Rubber Chemistry, American Chemical Society, Cleveland, Ohio, October 1971.

Ayrey, G, Barnard, D and Houseman, T H (1974) "The synthesis of tritium labelled dialkenyl sulphides structurally related to sulphur crosslinks in vulcanized natural rubber".
J Labelled Compound, 10, (1), 121

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Houseman, T H and Heneage, E (1973)
"Studies of cigarette smoke transfer using radioisotopically labelled tobacco constituents. Part I - The preparation of radioisotopically labelled cigarettes".
Beitrage Zur Tobakforschung, 7, (3), 138

Houseman, T H (1973)
'Studies of cigarette smoke transfer using radioisotopically labelled tobacco constituents. Part II - The transference of radioisotopically labelled nicotine to cigarette smoke".
ibid, 7, (3), 142

NB This paper was also presented at the 25th Tobacco Chemists Res Conf, Louisville, Kentucky, USA, 1971

Davis, B R, Houseman, T H and Roderick, H R (1973) "Studies of cigarette smoke transfer using radioisotopically labelled tobacco constituents. Part III - The use of dotriacontane-16, 17-^{14}C as a marker for the deposition of cigarette smoke in the respiratory system of experimental animals".

Armitage, A K, Houseman, T H, Turner, D M and Wilson, D A (1974) "The evaluation of a machine for introducing tobacco smoke into the lungs of anaesthetized animals during spontaneous respiration".
Quart J Exp Physiol, 59, 43

Armitage, A K, Houseman, T H and Turner, D M (1974)
"The transfer of endogenous and exogenous radioisotopically labelled nicotine to mainstream cigarette smoke and its absorption into the blood of anaesthetized cats".
ibid, 59, 55

Hopper, J B and Houseman, T H (1974)
"The transference of endogenous and radioisotopically labelled exogenous nicotine to cigar smoke".
Tobacco Science, 18, 160

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

NB This paper was also presented at the 27th Tobacco Chemists Res Conf., Winston-Salem, North Carolina, October 1973.
Armitage, A K, Dollery, C T, George, C F, Houseman, T H, Lewis P J and Turner, D M.
"Absorption and metabolism of nicotine by man during cigarette smoking".
Brit J Clin Pharmac

Armitage, A K, Dollery, C T, George, C F, Houseman, T H, Lewis, P J and Turner, D M (1975) "Absorption and metabolism of nicotine from cigarettes".
Br med J, 4, 313

Armitage, A K, Dollery, C T, Houseman, T H, Kohner, E M, Lewis, P J and Turner, D M (1977)
"Absorption of nicotine by man during cigar smoking".

Houseman, T H, Macfarlane, E A, Pullinger, D H, and Simons P J (1977)
"A single animal smoking system for exposing rats and other rodents to cigarette smoke".
J Aerosol Sci, 8, 111

Houseman, T H and Pullinger, D H
"Dosimetry of cigarette smoke (and other aerosols) in laboratory animals".
Clinical Toxicology, Proceedings of the European Society of Toxicology, Volume 18, ICS No 417, Amsterdam - Oxford, Exorpa Medica, 1977, pp 265 - 266

Binns, S H, Houseman T H and Phillips, K (1978)
"Synthesis of high specific activity tritium - labelled dotriacontane P
J Labelled Compounds and Radiopharmaceuticals, 14, (2), 163
Armitage, A K, Dollery, C T, Houseman, T H, Kohner, E M, Lewis, P J and Turner, D M (1978)
"The absorption and metabolism of nicotine from cigars".
Clin Pharmcol Ther, 23, (2), 143

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

2. SCIENTIFIC PRESENTATIONS

Barnard, D, and Houseman, T H (November 1969) "The application of radiochemical methods to the study of oxidation of natural rubber". Symposium on Oxidation, Hall of Fame Ceremony, Institute of Polymer Science. Akron University, November 1969.

Houseman, T H and Heneage, E (1973)
"Studies of cigarette smoke transfer using radioisotopically labelled tobacco constituents. Part I - The preparation of radioisotopically labelled cigarettes".

Hopper, J B and Houseman, T H (1974)
"The transference of endogenous and radioisotopically labelled exogenous nicotine to cigar smoke".

3. OTHER DETAILS

Chartered Chemist; Honorary Representative of the Royal Society of Chemistry; Past Member of the Committee of the Central Yorkshire Section of the Royal Society of Chemistry and the programme sub-committee; Chairman of Hazleton Client Awareness Working Party; Member of Hazleton Customer Satisfaction Steering Group; Member of Hazleton Biotechnology Steering Group.

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

R: REDACTED MATERIAL

PE11

CURRICULUM VITAE

1. PERSONAL DETAILS

Name: TENNANT, Karen Ann (née Bremner)

Date of Birth: REDACTED

Job Title: Scientist and Study Director, Department of Biopharmaceutical Analysis

Education:

1982 - 1986 BSc. (Hons in Applied Chemistry) Coventry Lanchester Polytechnic

2. PRESENT EMPLOYMENT

Hazleton UK.

1990 July - Scientist and Study Director, Department of Biopharmaceutical Analysis. (formerly Bioanalytical).
Responsibilities as for Study Director role below. Since September 1991 responsible for Special Methods group; responsible to the Head of Department

1989 - 1990 June Study Director, Bioanalytical Department. Responsible for the supervision of projects within the department to ensure good scientific and commercial management. This includes close liaison with sponsors as well as the Section Manager.

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2. PRESENT EMPLOYMENT - comtinued

1989 - 1990 June	Supervision and training of junior and graduate staff is a further responsibility
1986 - 1989	Study Supervisor, Biofluids Analysis. Responsible for the day to day performance of routine assays and assisting in method development and validation work for the measurement of drug levels in body fluids using gas and high performance liquid chromatography. Supervision of technicall staff allocated to specific studies

3. PAST EMPLOYMENT

1984 - 1985	Ministry of Agriculture, Fisheries and Food. Industrial Placement for BSc course. Analysis of amimal feeds, soils and dairy produce, including investigation into sulphate determination using HPLC and Dionex Ion Exchange Chromatography

4. TRAINING COURSES

1987	Jones Chromatography Solid Phase Extraction (one day seminar)
1988	Jones Chromatography Advanced Solid Phase Extraction (one day seminar)
1988	Total Quality Phase I Course (HUK)
1988 - 1989	Chemistry Training Modules for Study Supervisors

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4. TRAINING COURSES - continued

1989	Hazleton UK Course in Chromatographic Techniques at Leeds Polytechnic (10 day course)
1989	ESA Coulochem Electrochemical Detection (2 days, Severn Analytical)
1989	Total Quality Refresher Course (HUK)
1990	2nd International Symposium on Pharmaceutical and Biomedical Analysis (took part in poster presentation) (3 days)
1990	The Royal Society of Chemistry (Analytical Division, Autumn meeting) "Biomedical and Pharmaceutical Chemistry". (2 day seminar)
1990	"Advances in Capillary Gas Chromatography" by Professor Walter Jennings (1 day)
1990	World Class Quality Course (HUK)
1991	Management Skills Course (HUK 5-day)
1991	Bioanalysis of drugs, including anti-allergics and anti-asthmatics. 9th International Bioanalytical Forum (4-day seminar)
1991	Capillary Chromatography Seminar (1-day) (Restek Corporation/Thames Chormatography)

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5. PROFESSIONAL SOCIETY

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Signature: Norm Tennant

Date: 4 February 1992

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R: REDACTED MATERIAL

PE11

CURRICULUM VITAE

1. PERSONAL DETAILS

Name: MOORE, Jeff

Date of Birth: REDACTED

Job Title: Study Director, Bioanalytical Department

Education: 1979-1982 Kingston Polytechnic.
B.Sc. Bioanalytical Science Option of
Applied Science degree 2(i)

2. PRESENT EMPLOYMENT

Hazleton UK

1986- Study Director in Bioanalytical Department. Responsible for the supervision of projects within the section to ensure good scientific and commercial management. This includes close liaison with clients as well as the section manager. Supervision and training of junior and graduate staff is a further responsibility.

3. PAST EMPLOYMENT

1983-1986 Beecham Pharmaceuticals Research Division
Analytical Chemist in Pharmacokinetics Unit.
Responsible for method development and routine assay of biofluid samples generated by toxicology studies

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

and clinical trials as well as the reporting and pharmacokinetic interpretation of results.
Responsible for training of junior staff in the use of VG Multichrom data capture system.

4. TRAINING COURSES

1983	Pharmacokinetics Training Course (Dr. P.E. Coates DMPD Beecham Harlow)
1984	Laboratory Animal Handling (introductory course for potential Home Office licensees)
1984	Solid-Phase Extraction Techniques (Analytical Symposium)
1984	VG Multichrom Training Course
1985	Communication and Report Writing Workshop
1986	Statistics for Industry : 2 modules i) Basic statistical techniques ii) Statistics for Research and Development
1986	Pharmacokinetics and Drug Disposition
1987	Management and Supervision training course 8 one day modules (Scott-Grant)
1987	Report Writers Course
1987	Solid-Phase Extraction Techniques
1987	Total Quality Phase I Course
1988	Report Writers Refresher Course

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1988	International Symposium on Biomedical Applications of liquid chromatography (Bradford, UK).
1989	Total Quality Refresher Course
1989	Chemistry Training Modules for Study Supervisors
1990	2nd International Symposium on Pharmaceutical and Biomedical Analysis (York, UK).
1990	18th International Symposium on Chromatography (Amsterdam, Netherlands).
1990	World Class Quality Course

5. PROFESSIONAL QUALIFICATIONS

1989	Chartered Chemist and Member of Royal Society of Chemistry

6. PUBLICATIONS

1990	Automation of a HPLC assay for the determination of nicotine, cotinine and 3-hydroxycotinine in human urine.
	J. Biomed and Pharm Anal (Accepted for publication).
1990	On-line sample preparation and analysis of nicotine, cotinine and 3-hydroxycotinine and conjugates in human urine using a Gilson-AASP system.
	Jl. Chromatogr Biomed Appl (Accepted for Publication).

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

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PEll

CURRICULUM VITAE

1. PERSONAL DETAILS

Name:	FREEMAN, John Michael Howard
Date of Birth:	**REDACTED**
Job Title:	Senior Scientist, Residues Chemistry, Department of Metabolism and Environmental Chemistry

Education:

1958-1964	Reade Grammar School, Drax O level: English Language, English Literature, Art, French, History, Physics, Geography, Mathematics, Agricultural Science, Physics with Chemistry, Physics
1965-1967	Kitson College, Leeds ONC in Sciences.
1967-1970	Leeds Polytechnic HNC in Chemistry
1970-1974	Sheffield Polytechnic BSc Hons in Applied Chemistry (2:2)

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2. PRESENT EMPLOYMENT

Hazleton UK

Mar 1991 — Senior Scientist, Residues Chemistry
Study Coordinator responsible for coordinating the design and maintaining the Residues study schedules, and reporting performance statistics for Residues, Physical Chemistry and Environmental Fate. Also controlling the QA audit trail for these groups. The role also includes the collation of financial information and its provision to the Section Manager

1988 - Mar 1991 — Senior Study Director, Residues Chemistry
Acted as the focal point of study control and has overall responsibility of the scientific and technical conduct of the studies, as well as the interpretation, documentation and reporting of results. Maintains close liaison with clients on scientific matters and study status. Prepares PBUs and protocols. Responsible for the supervision and training of four staff

3. PAST EMPLOYMENT

1984-1988 — Senior Research Chemist at Dow Chemical Co, Letcombe Regis, Oxfordshire
Worked in the Residue Environmental Metabolism Group. Responsibilities included the supervision of students during industrial training, developing methods of analysis, liaising with various groups within the company, producing reports necessary for registration authorities, organisation and supervision of "one off"

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3. PAST EMPLOYMENT continued

	type residue studies, eg operator monitoring studies. Responsibilities also included the implementation of the Zymark laboratory robot to perform routine residue analysis. Acted as work permit signatory and first aider within the group
1980	Research Chemist at Dow Chemical Co Graduate Chemist at Dow Chemical Co
Aug 74 - May 77	Analytical Chemist at Ciba-Geigy Ltd, Whittlesford, Cambridge. Initially the same as above. Latterly was responsible for the determination of residues in a variety of matrices, working with one assistant
Jan 73 - Sep 73	Temporary Assistant at Ciba-Geigy Agrochemicals Ltd, Whittlesford, Cambridge. Assisted in the analysis of residues of pesticides and their metabolites in crops, soils and water, and also of the company's development and marketed products
Aug 71 - Dec 71	Temporary Assistant at the Ministry of Agriculture, Fisheries and Food, Harpenden. Assisted in inter-laboratory collaborative trials, the results of the work being forward to the PAC (Pesticide Advisory Committee)
1964-1970	Laboratory Assistant at BOCM Ltd, Selby. Assisted in the analysis of oils and fats, boiler waters and the raw materials of the cattle, pig and poultry feeds marketed by

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3. PAST EMPLOYMENT continued

the company. During the latter part of the employment, was involved in special projects, reporting directly to the Chief Chemist. Completed part-time studies, ONC Sciences and HNC in Chemistry, whilst in this job

4. TRAINING COURSES

Jun 1988	Quality course run by HUK.
Mar 1989	Lotus Freelance 3.01, Manchester
Mar 1989	Follow-up Quality course run by HUK.
Jul 1989	GLP course, Cambridge.
1990	WordPerfect 5.1 run by HUK
Sep 1990	COSHH training course run by Occupational Hygiene Services at HUK
Dec 1990	5-day training course on "Management skills" run by HUK
Jun 1991	Lotus 123 course run by International Software at HUK

5. PROFESSIONAL SOCIETIES

REDACTED

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Signature: John McTernan Date: 28 January 1993

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

R: REDACTED MATERIAL

HUK Study no 12/64

PE11

HAZLETON UK

CURRICULUM VITAE

1. PERSONAL DETAILS

Name: HOWARD, David Albert

Date of Birth: REDACTED

Job Title: Senior Scientist, Residues Chemistry, Department of Metabolism and Environmental Chemistry

Education:

1973-1977 University of Manchester Institute of Science and Technology
BSc Hons in Chemistry

2. PRESENT EMPLOYMENT

Hazleton UK

1986 - Supervisor, Instrument Laboratory and Chromatographic data processing; Data System Manager, Chemistry Services
Responsible for all personnel and equipment allocated to the Instrument Laboratory and Chromatographic data processing function in order to provide an efficient service to Chemistry operations. Includes identification of future requirements in terms of both human and physical resources and initiating action to ensure these are

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1987	HP3350A (LAS) System Managers Training Course (Hewlett-Packard)
1987	Management and Supervision Training Modules
1988	Fortran Computer Programming Course
1989	Lotus Freelance Plus Training Course
1989	Management of Information Systems and Information Technology
1989	Total Quality Refresher Course
1990	Wordperfect (Basic) Training Course
1990	Management Skills Course
1991	Use of Base-Deactivated HPLC columns
1991	Wordperfect (Advanced) Training Course
1992	Network Awareness
1992	Management Skills Course
1992	Paradox Introduction Training Course

5. PROFESSIONAL SOCIETIES

REDACTED

Signature: D Howard

Date: 5 May 1993

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

R: REDACTED MATERIAL

HUK Study no 12/64

BESSELAAR
Clinical Research Unit

CURRICULUM VITAE

1. PERSONAL DETAILS

Name: BRIDGER, Gillian

Date of Birth: REDACTED

Job Title: Marketing Executive
Besselaar Clinical Research Unit

Start date:

Education: 1966-1972 Allerton Grange

1965-1975 Yorkshire College of Music and Drama (Part-time)

2. PRESENT EMPLOYMENT

G H Besselaar & Associates
CRU Ltd - 1991

Marketing Executive
Besselaar Clinical Research Unit

Responsible to Managing Director

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3. PAST EMPLOYMENT

1989-1991	Besselaar Clinical Research Unit Recruitment Manager
1987-1989	Hazleton UK Business Development Assistant
Aug 1987-Oct 1987	Pic Toys, Harrogate Personal Assistant to the Director
Jan 1986-Jul 1987	Solicitors (Company name required) Legal Secretary to Senior Partner
1980-1986???	Guardian Preservation, Leeds Secretary to the Director
1979-1980	Leeds General Infirmary, Leeds Medical Social Work Department Medical Secretary
1977-1979	Bellow Machine Co. Ltd, Leeds Secretary
1974-1977	Leeds Traffic Area (Civil Servant) Junior Shorthand Typist
1972-1974	Meanwood Park Hospital, Leeds Junior Shorthand Typist

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Signed ..... Dated 23 4 93

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APPENDIX 2

SELECTION OF SUBJECTS

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

1. SUMMARY

The 327 subjects required for this study were selected from a data base held and controlled by Besselaar, Leeds, England. This data base contains approximately 15,000 subjects for use on clinical trials, involving the general public, on studies conducted by Besselaar on behalf of the Pharmaceutical industry. The following criteria were used in order to select possible subjects for use on this study.

1. That they were aged between 20 and 60

2. That they were non-smokers

3. That they worked and/or lived in the Leeds or Harrogate postal area

A sub-set of approximate 3000 possible subjects was selected and each was contacted by letter containing an information pack. Approximately 1000 subjects responded from which the 327 used on the study were selected on a first come first serve basis. This allowed for availability on appointment times, changes of mind etc etc.

2. SUBJECT CONTACT PROCEDURE

To ensure satisfactory responses once selected the following procedure was followed:

1. A first letter containing an information pack was sent out to each of the 3000 selected subjects (See Appendix 2.1).

2. The subjects then contacted the Besselaar Recruitment Department. At this stage it was established that the subject was a non-smoker. A questionnaire was completed by the recruiter (See Appendix 2.2).

3. The responses were collated and a second letter sent out by postal district to establish an appointment date (See Appendix 2.3).

4. Finally reminder letters were sent out 2 to 6 days prior to the agreed appointment (See Appendix 2.4).

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APPENDIX 2.1

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

WOULD YOU LIKE TO TAKE PART IN AN AIR QUALITY SURVEY?

CAN YOU CARRY A MONITOR FOR 24 HOURS?

STUDY NUMBER 12/64

We are looking to recruit 300 non-smoking male and female volunteers aged between 22 and 60 years to take part in a 24 hour air monitoring study. Anyone living in Harrogate or Leeds is eligible to take part.

This study involves no in-patient stay, no medical, no blood samples and no restrictions on diet or drink. It will not compromise studies done in the past or prevent you from taking part in future studies.

You will be required to wear a monitor (picture enclosed) for a 24 hour period, only removing it to shower and to sleep.

The monitor pumps air through a filter and it is the filter that will be analysed to see what has passed through it.

Two saliva samples will be collected, one at the start and one at the end of the 24 hour period, and you will be required to keep a simple hourly diary throughout the monitoring period.

The monitor will be delivered to you on a specified day at a specified time at your home address (or that of your place of employment, providing it is within the Harrogate or Leeds area) and will be collected from the same address exactly 24 hours later. You will be required to spend approximately 20 minutes with our staff. You should therefore have access to a suitable area to allow collection of the saliva samples and completion of the questionnaire.

Volunteers will be monitored at a rate of 5 per day commencing at the end of September and running through October and November. To take part you must be at your home (or work) address during at least one of the timeframes listed below to enable us to schedule delivery and pick-up.

1. 0700 - 0900 Monday to Sunday
2. 1200 - 1400 Monday to Sunday
3. 1600 - 1800 Monday to Sunday

THE PAYMENT FOR THIS STUDY IS £55

If you are interested in taking part then please telephone Recruitment on 0800 591 570.

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

APPENDIX 2.2

2023686445

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

STUDY NUMBER 12/64

NAME:		
AGE:		
ADDRESS:		
OCCUPATION:		
QUESTIONNAIRE	YES	NO
Do you work in a factory		
Do you work in a shop		
Do you work in an office		
Do you work indoors		
Do you work outdoors		
Are you exposed to pollen		
Do you drive		
Do you spend much time in traffic		
Are you at home most evenings		
Do you cook most evenings		
Do you have central heating		
Do you have a coal fire		
Do you have a gas fire		
Do you have an electric fire		
Do you live near a main road		
Do you have good ventilation at home		
Do you smoke		
Does your spouse smoke		
Does anyone else in the household smoke		
Are you exposed to tobacco smoke at work		
Are you exposed to tobacco smoke at leisure		

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

APPENDIX 2.3

2023686447

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

G H. Besselaar Associates
Springfield House
Hyde Street
LEEDS LS2 9NG, UK
Phone (0532) 448071
Fax (0532) 445600

Clinical Research

23 September 1992

BESSELAAR

Dear

You have been selected to take part in the Air Quality Survey which is due to commence on Tuesday 6th October 1992.

Please note that the timings for delivery and collection of the monitors have changed..

Work or Home address in Leeds	0900 - 1200 hours
Work or Home address in Harrogate	1400 - 1700 hours

You will have to be available either at home or at work between the above hours, as it will be impossible for us to give an exact time for delivery/collection of the monitors.

Five monitors will be delivered every day (including Saturday and Sunday) commencing on Tuesday 6th October until 280 results have been recorded. It is hoped that the study will finish after 7/8 weeks. Volunteers will receive their payment 10-14 days after they have successfully completed the 24 hour monitoring period.

Given the above information, if you are still available to take part in the study, please give Julie a ring on the free phone number (0800 591 570) so that we can issue you with a date and take a note of the address you wish the monitor to be delivered/collected from.

2023686448

G H Besselaar Associates (UK) Ltd
Registered in England No 2655166
Registered Office as above

Brussels Belgium
Maidenhead, UK
Leeds UK
Munich Germany
Zurich Switzerland
Paris France
Stockholm, Sweden
Dublin, Ireland

Princeton USA
Nashville USA
St Davids USA
Marion USA
West Palm Beach USA
Sydney, Australia
Tokyo Japan

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

APPENDIX 2.4

2023686449

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

HUK Study no 12/64

G H Besselaar Associates
Springfield House
High Street
[illegible] 9NG UK
Phone (0532) 448071
Fax (0532) 445600

1992

BESSELAAR

Dear Sir/Madam

Re: Study 12/64

Thank you for making an appointment for Project 12/64, the Air Quality Study.

This letter is just to remind you that your appointment will be on:

Between the hours of:

It is important that you are available between these hours as we cannot determine the exact time of arrival.

Thank you for your co-operation.

Julie Form
Volunteer Selection Officer

Besselaar Clinical Research Unit

2023686450

G H. Besselaar Associates (UK) Ltd
Registered in England No. 2655166
Registered Office as above

Brussels, Belgium
Maidenhead UK
Leeds UK
Munich Germany
Zurich Switzerland
Paris France
Stockholm Sweden
Dublin, Ireland

Princeton USA
Nashville USA
St Davids USA
Macon USA
West Palm Beach USA
Sydney Australia
Tokyo Japan

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Page 2
Air Quality Survey

We do appreciate that there will be times when the delivery and collection addresses will be different, i.e. when the delivery is on a weekday and the collection falls on a weekend. Again, this will be coordinated by the Recruitment Team when you call.

If you require any further information, please do not hesitate to contact Recruitment on the free phone number.

Yours sincerely

Julie Form

Volunteer Recruitment

2023686451

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

APPENDIX 3

PROCEDURES FOR THE PERSONAL MONITORING PERIOD

2023686452

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

SUMMARY

Subjects' exposure to ambient nicotine and TSP from all sources is measured over a 24 hour period using a personal monitoring technique.

Air from the subjects' immediate vicinity is drawn through two filters in series held in a small filter holder using a battery-operated pump.

Saliva samples are taken from subjects at the beginning and end of the 24 hour monitoring period.

Subjects maintain a diary during the 24 hour monitoring period and a detailed questionnaire is completed at the end of the monitoring period.

2023686453

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

OUTLINE PROCEDURE

PREPARATION OF THE PERSONAL MONITOR FOR A MONITORING SESSION

CLEAN THE FILTER HOLDER AND ASSOCIATED PARTS.

PREPARE THE ACID TREATED FILTER.

WEIGH THE TEFLON FRONT FILTER.

ASSEMBLE THE FILTER HOLDER.

CONNECT THE PUMP AND CHECK THAT THE HOLDER IS LEAK-TIGHT.

SET THE PUMP FLOW RATE AND NOTE THE PUMP COUNTER READING.

APPLY SECURITY TAG.

SEAL THE FILTER HOLDER INLET AND OUTLET WITH CAPS.

ASSEMBLE A FILTER AS A BLANK CHECK.

2023686454

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

OUTLINE PROCEDURE.

STARTING THE MONITORING SESSION

TRAIN SUBJECT ON USING THE MONITOR AND USE OF THE DIARY.

TAKE SALIVA SAMPLE.

NOTE THE PUMP COUNTER READING.

REMOVE THE CAPS FROM FILTER HOLDER AND CONNECT PUMP.

CHECK THE SECURITY TAG.

START PUMP AND RECORD THE PUMP START TIME AND DATE.

2023686455

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

OUTLINE PROCEDURE

ENDING THE MONITORING SESSION:

THE MONITORING SESSION WILL END 24 HOURS AFTER IT STARTS.

SWITCH OFF THE PUMP.

NOTE THE PUMP COUNTER READING AND THE PUMP STOP TIME.

CHECK THE SECURITY TAG.

SEAL THE FILTER HOLDER INLET AND OUTLET WITH CAPS.

TAKE SALIVA SAMPLE.

COMPLETE THE QUESTIONNAIRE AND COLLECT THE DIARY.

2023686456

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

OUTLINE PROCEDURE

FINAL CHECKS PRIOR TO ANALYSIS

CHECK INTEGRITY OF SECURITY TAG.

NOTE THE PUMP COUNTER READING.

CHECK THE HOLDER IS LEAK TIGHT.

CHECK PUMP FLOW RATE.

2023686457

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

EQUIPMENT

1. MICROBALANCE

Sartorius model M3P (six decimal place) or equivalent. The balance should be mounted on a very stable surface and situated in a temperature controlled laboratory away from strong draughts.

The microbalance should stand on an earthen antistatic mat. During microweighing, the operator should be connected to this mat via an antistatic wrist-band strap. This arrangement eliminates static charge build-up arising from the operator and ambient conditions during microweighing.

2. CHECK-WEIGHT FOR MICROBALANCE

A 20 mg calibration weight was used as a check weight throughout the study. This weight is approximately the same as the weight of a Millipore Filter.

3. RADIOACTIVE SEALED SOURCE STATIC ELIMINATOR

BAR-TYPE:	POLONIUM-210 (approximately 148 M Bcq)
CATALOGUE NUMBER:	PDV 1
SUPPLIER:	Amersham International PLC, Buckinghamshire, England.

Polonium-210 radioactive static eliminators have a working lifetime of approximately one year.

4. FLUOROPORE MEMBRANE FILTERS

DIAMETER:	25 mm
PORE SIZE:	1 μm
CATALOGUE NUMBER:	FALP 02500
SUPPLIER:	Millipore UK Ltd, Hertfordshire, England.

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

5. PALLFLEX FILTERS

DIAMETER:	25 mm
CATALOGUE REFERENCE:	FIBERFILM T60A20
SUPPLIER:	PALLFLEX CORPORATION, Putnam, Connecticut, USA

6. FILTER HOLDERS AND PERSONAL MONITOR FITTINGS

As supplied by Study Sponsor. (See Appendix 3 Figure 1 - Filter Holder). (Appendix 3 Figure 2 - Filter Holder and Pump as Worn by Subject).

The pump is contained in a bag on a waist belt worn by the subject. These bags are commercially available but additional felt sound proofing was added to further reduce pump noise. The felt was sealed in polythene to prevent release of fibrous materials.

7. CONSTANT FLOW AIR SAMPLING PUMPS

MODEL NUMBER:	222-3
SUPPLIER:	SKC Ltd, Dorset, England

8. AIRFLOW CALIBRATOR FOR PUMPS

TYPE:	Gilibrator Soap-Film (20 mL/min to 6 l/min flow cell)
MANUFACTURER:	Gilian Instrument Corp, New Jersey, USA
SUPPLIER:	Eden Scientific, Surrey, England

9. EQUIPMENT FOR SALIVARY COTININE SAMPLE COLLECTION

SALIVA SAMPLING EQUIPMENT:	Salivette
SUPPLIER:	Sarstedt, Beaumont, Leys, Leicester, England. (See Appendix 3 Figures 3, A and B).

10. SECURITY TAG

26 SWG Nichrome wire.

Uninsulated crimp connectors (Radiospares 532 670).

Crimper (Radiospares 532 636).

2023686459

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

PREPARING THE PERSONAL MONITOR

CLEANING AND PREPARATION OF THE HOLDER

Wash the filter holder body and the Teflon spacers in hot water containing a little detergent. Rinse these parts in distilled water and then in methanol. Dry all parts in an oven at 100°C and store in a smoke-free area.

PREPARATION OF THE ACID-TREATED FILTER

Immerse the Pallflex filter in a fresh 4% solution of sodium bisulphate for 30 seconds. Remove the filter and allow excess liquid to drain off. Place the filter on a clean watch glass and allow it to dry for a minimum of one hour in a desiccator. Store in the desiccator or a closed vessel until ready for use. (See Appendix 3 Figure 4).

NB: It is essential that these filters are dry before use or they will block completely on pumping.

These filters will absorb nicotine from the atmosphere.

WEIGH THE TEFLON FRONT FILTER

Ensure the balance has gone through its daily calibration check and that the check-weight is within 1 μg of the last check and 2 μg of the expected value determined at the start of the project.

Attach the earthing strap to a wrist before using the balance.

Handle the filter only with stainless steel tweezers and hold the filter under the static eliminator at a distance of 5 cm for about 10 seconds before each weighing.

Weigh the filter five times or until five consecutive weighings are each within a total range of 3 μg. Record the average weight of these five weighings. (See Figure 5).

If the balance calibration is not within the specified range, on a given day, correct the filter weight by the difference between the check weight and its expected weight.

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

ASSEMBLE THE FILTER HOLDER

Using fine pointed stainless steel tweezers place the filters and Teflon spacers in the filter holder body as in the arrangement shown in Appendix 3 Figure 1.

Note that the dull face of the Millipore filter and the rough, cream face of the Pallflex filter should face the air inlet.

Assemble the entrance plate to the filter holder body ensuring that it fits over the rubber 'O' ring properly.

Screw on the clamping cover firmly.

Cap the filter holder inlet and outlet until ready for leak testing.

CONNECT THE PUMP AND CHECK THAT THE HOLDER IS LEAK-TIGHT

Remove the caps from the filter inlet and outlet.

Using a fully-charged pump, adjust the flow rate to 142 mL/min. Connect the pump inlet to the filter holder outlet using the plastic tubing provided, ensuring a tight connection at the pump and the filter holder.

Replace the tubing if a tight seal cannot be obtained.

Remove the cap from the filter holder inlet.

Turn on the pump briefly and ensure that it is running properly. Cap the filter holder inlet and check that the pump comes to a stop within 10 seconds. If the pump continues to run then the filter holder is not leak tight and should be checked.

Once the filter holder is leak tight attach the security tag by passing the Nichrom wire through two aligned holes in the filter holder and applying the crimp.

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

STARTING THE MONITORING SESSION

TRAINING THE SUBJECT ON USING THE MONITOR AND USE OF THE DIARY

Explain to the subject that the study is looking at air quality but do not mention that the primary purpose relates to cigarette smoke.

Show the subject how to wear the monitor and how to take it on and off when changing clothes or going to bed. Ask if he/she has any objection (eg safety) to wearing the monitor with the 'necklace'. Offer the use of safety pins if this is the case.

Ask the subject not to let the monitor interfere with normal behaviour.

Instruct the subject not to interfere with the monitor and not to let anyone else interfere with it. Explain that tampering with the monitor will be detected and will result in loss of the subject's reward.

Provide the subject with the security letter which explains that he/she is involved in an air quality study conducted by Hazleton. (See Appendix 3 Figure 7).

Explain that the subject should remove the monitor when he/she goes to bed and place the monitor nearby and upright such that the air inlet is not obstructed. If the pump is found to be too noisy during this time, the belt bag containing the pump can be placed in a larger bag or covered with a pillow. The filter holder must not be obstructed or covered in any way and the plastic tube connecting the pump to the filter holder must not be kinked.

Instruct the subject to complete the diary for each hour awake during the monitoring period. The main requirement is to record location, activity and factors which might affect air quality, including smoking. (See Appendix 3 Figure 8, pages 1 to 3).

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

SET THE PUMP FLOW RATE AND RECORD THE PUMP COUNTER READING

Remove the cap from the filter holder inlet.

Connect the outlet of the pump to the flow meter and check the pump flow rate is between 136 and 142 mL/min. Record the flow rate. This work should be done in a clean area where no smoking is allowed and air should not be pumped through the assembled filter for more than two minutes. The amount of contamination of the filter in this time is negligible.

Record how many pump strokes are registered on the counter in a 1.00 minute period (approximately 250 depending on the individual pump). This figure will be used to check correct operation of the pump during the 24 hour sampling period.
(See Appendix 3 Figure 6).

Detach the plastic tubing from the filter holder outlet.

Cap the filter holder inlet and outlet.

Record the pump stroke counter reading.

ASSEMBLE A FILTER HOLDER AS A BLANK CHECK

For each series of personal monitors assembled on a given day, assemble one blank holder. Attach a pump and set the flow rate in the same way as for the other monitors. Cap the holder and retain until the group of personal monitors is returned for analysis.

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TAKE SALIVA SAMPLE

Remind the subject that a saliva sample is required at the beginning and end of the sampling period. Reassure the subject if necessary that only a chemical test and no medical tests will be done on the sample.

Collect the saliva sample according to the procedure in Figures 3, A and B.

Check that the sample tube is correctly labelled with the subject's code number and the date. Also ensure that the tube is labelled "pre-sample".

Centrifuge the salivette and transfer to a freezer (-20°C) as soon as possible and retain there until ready for use.

CONNECT THE PUMP AND RECORD THE PUMP COUNTER READING

Fit the pump into the belt bag with the plastic tubing passing through the hole provided in the bag.

Remove the filter holder outlet cap and connect the plastic tubing from the pump to the filter holder.

Record the pump stroke counter reading.

REMOVE CAP FROM FILTER HOLDER

Remove the filter holder cap from the air inlet. Do not leave the caps with the subject.

FIT THE MONITOR, START THE PUMP AND RECORD THE PUMP START TIME

Attach the 'necklace' to the filter holder and fit the personal monitor to the subject. Safety pins can be used in place of, or in addition to the necklace if necessary for a particular subject.

Switch on the pump and ensure that it runs at normal speed for at least 30 seconds. Record the pump start time.

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Close the belt bag.

Confirm the appointment for the end of sampling period in 24 hours time.

NB: A check list was carried by the investigator (See Appendix 3 Figure 10) to ensure study compliance at the beginning and end of the monitoring period. This was essential to ensure smooth running of the study and minimise the effect of outside distractions (eg children, telephone calls, visitor's questions etc).

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

ENDING THE MONITORING SESSION

The monitoring session should end as close as possible to 24 hours after it started and certainly not at less than 23 hours or more than 25 hours.

SWITCH OFF THE PUMP

Open the belt bag and check that the pump is running normally. Switch off the pump and record the stroke counter reading and the switch-off time.

Check the security tag.

Disconnect the pump and cap the filter holder.

Take a saliva sample by the same procedure as at the start of the monitoring session.

Check that the sample tube is correctly labelled with the subject's code number and date and that it is a 'post-sample'.

Centrifuge the salivette and transfer to a freezer (-20°C) as soon as possible and retain there until ready for use.

COMPLETE THE QUESTIONNAIRE AND COLLECT THE DIARY

Do not explain to the subject that the main purpose of the study relates to cigarette smoking.

Complete the questionnaire as well as possible, (see Appendix 3 Figure 9, sections 1 to 6) making use of the diary to get answers which are as accurate as possible.

Collect the diary from the subject and keep it together with the questionnaire.

NB: Note the check list (Appendix 3 Figure 10):

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FINAL CHECKS ON RETURN TO THE LABORATORY PRIOR TO ANALYSIS

CHECK THAT THE SECURITY TAG IS INTACT

If the tag is not intact and was found not to be intact by the interviewer at the end of the sample period, do not proceed with the analysis.

RECORD THE PUMP STROKE COUNTER READING

Record the pump stroke counter reading.

Check that the laboratory record of stroke counts corresponds with those recorded by the interviewer for the start and end of the monitoring session.

Ensure that the total stroke counts recorded during the sampling session are consistent with continuous sampling for 24 hours using the stroke count rate determined when setting the flow rate.

CHECK THE HOLDER IS LEAK TIGHT

Remove the cap from the filter holder outlet and attach the pump.

With the filter holder inlet still capped, turn the pump on. The pump will stop within 10 seconds if the pump is leak tight. Record the result of this test.

CHECK THE PUMP FLOW RATE

Remove the filter holder inlet cap and measure the pump flow rate by connecting the pump outlet to the flow meter. The pump flow rate should be close to the 139 mL/min set prior to sampling and must be at least 120 mL/min.

Calculate and record the volume of the air sample collected in litres.

VA = (V1+V2)*T*/2000 litres.

Where:

V1 = pump flow rate at the start of sampling in mL/min.

V2 = pump flow rate at the end of sampling in mL/min.

T = duration of the sampling period in minutes.

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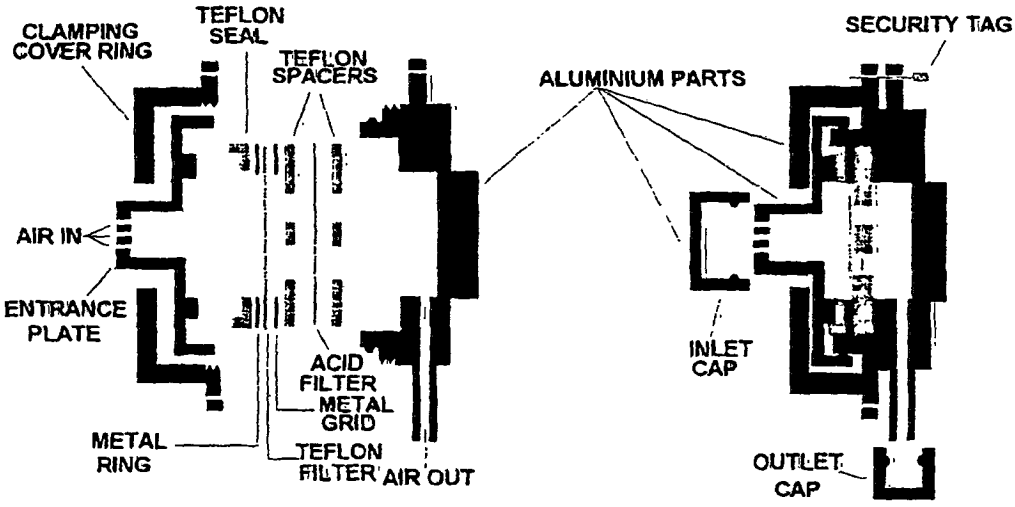
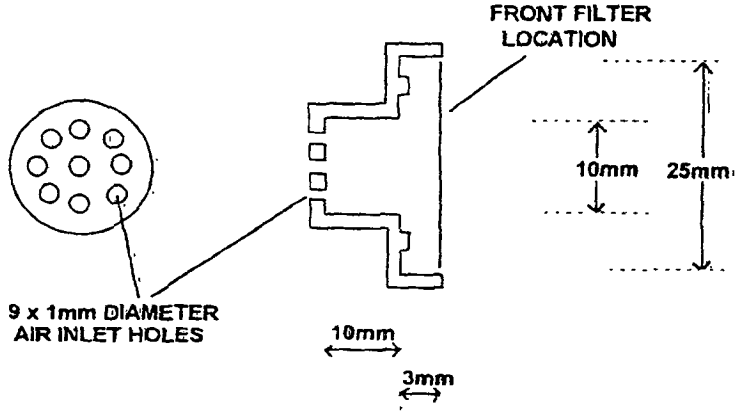
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

APPENDIX 3 FIGURE 1



FILTER HOLDER APART AND ASSEMBLED



ENTRANCE PLATE DIMENSIONS

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

APPENDIX 3 FIGURE 2

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

APPENDIX 3 FIGURE 3A

SALIVETTE INSTRUCTIONS FOR USE

COLLECTION OF SALIVA

1. The cylindrical shaped swab (b) is removed from the insert (c) and placed in the mouth.

2. The swab is chewed for 30 to 45 seconds or until one can no longer prevent swallowing the saliva produced.

   If the swab can not be chewed, it can be placed under the tongue for 30 to 45 seconds.

3. After the above procedure is complete, the swab is returned to the insert and the Salivette firmly closed with the stopper (a).

   Storage conditions are dependent upon specimen use and have not been established.

RECOVERY OF SALIVA

4. The Salivette is centrifuged for two minutes at 1000 x G. Higher G forces result in only slightly higher yields of saliva.

   During centrifugation, the saliva will pass from the cylindrical shaped swab through the hole in the bottom of the suspended tube into the clear centrifuge tube. Mucous strands and particles will be caught in the conical tip of the centrifuge tube allowing easy decanting of the clear saliva.

STOPPER (a)

SWAB (b)

INSERT (c)

CENTRIFUGE TUBE (d)

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

APPENDIX 3 FIGURE 3B

YOU HAVE BEEN ASKED TO PROVIDE A SALIVA SAMPLE: IT'S EASY! CAREFULLY READ AND FOLLOW THE STEPS BELOW.

1. Hold the vial in an upright position (cap at the top).

2. Remove the cap and hold the vial to your lips. (Do not touch the cotton pad with your fingers!).

3. Tilt the vial so that the cotton pad slides into your mouth.

4. Chew the cotton pad vigorously for a minute or two until the pad is completely saturated!

5. Place the vial to your lips and allow the cotton pad to slide back into the vial. DO NOT SPIT INTO THE VIAL and DO NOT USE YOUR FINGERS. If you need to, use your tongue to guide the pad back into the vial.

6. Put the cap back on the vial.

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

APPENDIX 3 FIGURE 4

STUDY : 12/64 **CHECK LIST** **ACTUAL STUDY**

PRIOR TO SAMPLE COLLECTION

The following table charts the analysis of Monitor units for despatch

on .....

TEST SYSTEM		MONITOR UNIT		TEFLON FILTER	NICOTINE FILTER		SALIVA POT		DONE
SUB	UNIT	WASH	DRY	WEIGHED	SOAKED	DRY	PRE	POST	D/I

AFTER SAMPLE COLLECTION

TEST SYSTEM		SALIVA SPIN DOWN		TEFLON FILTER	TEFLON FILTER EXTRACTION		NICOTINE EXTRACT	MCHROM SET-UP	ANALYSES CHROMY/DATA		
SUB	UNIT	PRE	POST	WEIGHED	UVPM/FPM	NICOT1	NICOT2	M/C/RS	LC	GC	DP

Comments :

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

APPENDIX 3 FIGURE 5

AIR QUALITY SURVEY - HUK STUDY NUMBER 12/64

PERSONAL DETAILS	
Volunteer number:	Name:
Monitor number:	Address:
	Postcode:

DETERMINATION OF TOTAL PARTICULATES

PRE-EXPOSURE: Calibration weight = _____ mg

Weighings performed by _____ Date: _____

wt filter 1 _____ mg

2 _____ mg

3 _____ mg

4 _____ mg

5 _____ mg Mean _____ mg (W1)

POST-EXPOSURE: Calibration weight = _____ mg

Weighings performed by _____ Date: _____

wt filter 1 _____ mg

2 _____ mg

3 _____ mg

4 _____ mg

5 _____ mg Mean _____ mg (W2)

TOTAL PARTICULATES

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

APPENDIX 3 FIGURE 6

DETERMINATION OF TOTAL VOLUME OF AIR (VA) COLLECTED (PROJECT NO 12/64)

SUBJECT DETAILS				
NAME:		SUBJECT NUMBER:		
ADDRESS:		POST CODE:		
EQUIPMENT				
PUMP NUMBER:		MONITOR NUMBER:		
MONITORING				
CALIBRATION DATE.		START DATE:	END DATE:	DIFFERENCE
Leak tested OK:	Y / N	Y / N	Y / N	
Tag OK:	Y / N	Y / N	Y / N	
Flow rate:	V_1:		V_2	
Count/minute:	C_1:		C_3	C_2-C_1:
	C_2		C_4	C_4-C_3:
Pump counts:				
Pump on/off (time):				Times
Saliva sample OK:		Y / N	Y / N	
Calibrated by:				
Operator/checked by:				

VA CALCULATION

$$V_A = (V_1 + V_2) \times T/2000 =$$

VA =	
Calculated by:	Date:
Checked by:	Date:

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

FLOW RATE CALIBRATION			
START		END	
Signed:	Date:	Signed:	Date:

2023686475

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

APPENDIX 3 FIGURE 7

Keith Phillips, CChem, FRSC
Manager, Department of Environmental Sciences

HAZLETON UK

Otley Road, Harrogate
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Telex: 57735
Telefax 0423 525620
GP4 569595
Cables Hazlabs Harrogate

Hazleton UK Ltd.
Registered in England No 1171833
Registered Office as above

TO WHOM IT MAY CONCERN

AIR QUALITY SURVEY - REFERENCE 12/64

The Department of Environmental Sciences at Hazleton UK is conducting an air quality survey as part of a study in the Yorkshire area. We are interested in all locations including homes, travel, workplaces, leisure situations etc.

As part of this survey, the volunteer will wear a monitor for 24 hours as they go about their daily lives. The volunteers and hence locations have been randomly selected and therefore do not imply any potential areas of poor air quality. The locations will not be specifically identified or mentioned by name in any report produced from this survey.

The monitor which does not need a power supply is contained in a small bag. It is quiet, unobtrusive and safe. The bearer of this letter will be wearing the monitor and can explain some of it's features if necessary.

If you require further information please contact me at the above address or telephone number during office hours, 0900-1700 Monday to Friday and quote reference 12/64. Messages can be left at any time out of office hours on the Volunteer Selection Freephone number 0800 591570.

Thank you in advance for your cooperation in this matter.

Yours sincerely

Keith Phillips
Manager, Department of Environmental Sciences
for Hazleton UK

2023686476

CORNING ... Services Company

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

APPENDIX 3 FIGURE 8

(PAGES 1 TO 3)

PAGE 1

INSTRUCTIONS FOR COMPLETION OF THE HOURLY DIARY

1. Please summarise briefly what you did in each hour of the study period and where you were at that time.

2. Please give brief details of any observations you think might have affected air quality.

3. Please indicate the air quality by ticking the yes or no box.

4. Please complete both page 2 and 3 of the diary.

5. If in doubt as to how to proceed, please telephone Recruitment free on 0800 591 570 during office hours (0845 - 1700 hours Monday to Thursday and 0845 - 1630 on Friday)

EXAMPLE

TIME	SUMMARY OF ACTIVITIES AND LOCATION	AIR QUALITY	YES	NO
1800 - 1900 hours	Cooked Tea Had a bath	Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking	✓ ✓	✓ ✓ ✓
1900 - 2000 hours	Watched T.V. Walked to pub through woods	Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking	✓ 	 ✓ ✓ ✓ ✓
2000 - 2100 hours	In pub	Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking	 ✓ ✓	✓ ✓ ✓
2100 - 2200 hours	Still in pub	Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking	 ✓ ✓	✓ ✓ ✓
2200 - 2300 hours	Walked Home along a road Watched T.V.	Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking	✓ 	 ✓ ✓ ✓ ✓
2300 - 2400 hours	Made Supper Went to bed	Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking	✓ ✓	 ✓ ✓ ✓

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

HUK Study no 12/64

PAGE 2

DIARY - PLEASE READ INSTRUCTIONS ON SHEET 1 CAREFULLY BEFORE COMPLETING				
TIME	SUMMARY OF ACTIVITIES AND LOCATION	AIR QUALITY	YES	NO
0600 - 0700 hours		Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking		
0700 - 0800 hours		Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking		
0800 - 0900 hours		Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking		
0900 - 1000 hours		Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking		
1000 - 1100 hours		Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking		
1100 - 1200 hours		Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking		
1200 - 1300 hours		Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking		
1300 - 1400 hours		Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking		
1400 - 1500 hours		Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking		
1500 - 1600 hours		Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking		
1600 - 1700 hours		Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking		
1700 - 1800 hours		Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking		

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

PAGE 3

DIARY - PLEASE READ INSTRUCTIONS ON SHEET 1 CAREFULLY BEFORE COMPLETING				
TIME	SUMMARY OF ACTIVITIES AND LOCATION	AIR QUALITY	YES	NO
1800 - 1900 hours		Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking		
1900 - 2000 hours		Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking		
2000 - 2100 hours		Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking		
2100 - 2200 hours		Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking		
2200 - 2300 hours		Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking		
2300 - 2400 hours		Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking		
2400 - 0100 hours		Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking		
0100 - 0200 hours		Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking		
0200 - 0300 hours		Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking		
0300 - 0400 hours		Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking		
0400 - 0500 hours		Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking		
0500 - 0600 hours		Good Ventilation Air Conditioning Paint Fumes Tobacco Smoke Cooking		

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

APPENDIX 3 FIGURE 9

(SECTIONS 1 TO 6)

Subject no

AIR QUALITY SURVEY QUESTIONNAIRE

SECTION 1

INTERVIEWER'S NAME.....

DATE.....

SUBJECT'S NAME.....

AGE.....

MALE/FEMALE.....

MARRIED/PARTNER/SINGLE.....

LIVING WITH SPOUSE/PARTNER.....

ADDRESS.....

POST CODE.....

OCCUPATION.....

OCCUPATION POST-CODE.....

2023686480

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HUK Study no 12/64

Subject no

AIR QUALITY SURVEY QUESTIONNAIRE

SECTION 2

1. DID THE MONITOR WORK PROPERLY FOR THE WHOLE TEST PERIOD?.....
2. WAS THE MONITOR KEPT IN YOUR VICINITY AT ALL TIMES? .....
3. WAS THE MONITOR INTERFERED WITH BY ANYBODY?.....
4. DID ANYONE DELIBERATELY BLOW SMOKE INTO THE MONITOR?.....
5. DID YOU SPEND ANY TIME IN A DUSTY ATMOSPHERE?.....
6. DID YOU SPEND ANY TIME NEAR HEAVY TRAFFIC?.....
7. IS YOUR HOME / ACCOMMODATION NEAR A BUSY ROAD?.....
8. WHICH AEROSOL SPRAYS/ OTHER SPRAYS/PERFUME SPRAYS DID YOU USE?

   .....
9. WHAT TYPE OF HEATING IS USED IN YOUR HOME/ACCOMMODATION?.....
10. DID YOU USE THE VACUUM CLEANER OR DID ANYONE ELSE USE IT WHILE YOU WERE THERE?.....
11. DID YOU DO, OR WERE YOU NEAR, ANY PAINTING OR DECORATING?.....
12. DID YOU DO, OR WERE YOU NEAR, ANY COOKING?.....
13. WAS ANY FRYING DONE WHILE YOU WERE NEARBY?.....
14. HOW DO YOU RATE THE GENERAL AIR QUALITY IN THE REGION WHERE YOU LIVE?

    Very Good Good Moderate Poor Very Poor

2023686481

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

HUK Study no. 12/64

Subject no

AIR QUALITY SURVEY QUESTIONNAIRE

SECTION 3

15. HOW DO YOU RATE YOUR AVERAGE EXPOSURE TO TOBACCO SMOKE DURING THE TEST PERIOD?

None * Low Moderate High Very High
* IF NONE PROCEED TO QUESTION 18

16. FOR HOW MANY HOURS OF THE TEST PERIOD WAS THE EXPOSURE TO TOBACCO SMOKE?

None.....Low.....Moderate.....High.....Very High.....
(TOTAL IS DURATION OF TEST PERIOD)

17. WHAT PERCENTAGE OF YOUR TOTAL EXPOSURE TO TOBACCO SMOKE IN THE TEST PERIOD DO YOU ESTIMATE THAT OCCURRED: (TOTAL IS 100%)

At home/accommodation.....At work.....In travel.....During leisure.....

18. HOW DID YOUR EXPOSURE TO TOBACCO SMOKE DURING THE TEST PERIOD COMPARE WITH YOUR AVERAGE EXPOSURE LEVEL OVER THE LAST SIX MONTHS? EXPOSURE IN THE TEST PERIOD WAS:

Much less than normal.

Less than normal.

Fairly typical of average exposure.

More than normal.

Much more than normal.

19. WHAT PERCENTAGE OF YOUR TOTAL EXPOSURE TO TOBACCO SMOKE IN THE LAST SIX MONTHS DO YOU ESTIMATE THAT OCCURRED: (TOTAL IS 100%).

At home/accommodation.....At work.....In travel.....During leisure.....

20. FROM THE FOLLOWING LIST CAN YOU PLACE IN ORDER THE FOUR MAIN SOURCES OF YOUR EXPOSURE TO TOBACCO SMOKE DURING THE LAST SIX MONTHS? (NUMBER AS 1 TO 4)

Work.....Travel.....Leisure.....Spouse/Partner.....Father.....Mother.....
Son.....Daughter.....Brother.....Sister.....Friends.....Other People.....
Own Smoking.....None.....

2023686482

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HUK Study no 12/64

Subject no

AIR QUALITY SURVEY QUESTIONNAIRE

SECTION 4

21. HOW MANY HOURS IN THE TEST PERIOD DID YOU SPEND AT HOME / ACCOMMODATION?.....

22. HOW MANY HOURS IN THE TEST PERIOD DID YOU SPEND AT WORK (EXCLUDING WORK-RELATED TRAVEL)?.....

23. HOW MANY HOURS IN THE TEST PERIOD DID YOU SPEND IN TRAVEL (INCLUDING WORK-RELATED TRAVEL)?.....***

24. HOW MANY HOURS IN THE TEST PERIOD DID YOU SPEND AT LEISURE?.....
(This does not include leisure at home)

(TOTAL TIME FOR HOME, WORK, TRAVEL AND LEISURE SHOULD BE DURATION OF TEST PERIOD)

DEFINITIONS

HOME Normal place of abode in recent weeks.

ACCOMMODATION Place of stay during the study period if not at home.

WORK** Occupation or employment but not housework or other work at own home.

TRAVEL All forms of transport unless a sporting activity.

LEISURE All time spent when not at home/accommodation, not at work and not in travel

2023686483

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Subject no

AIR QUALITY SURVEY QUESTIONNAIRE

SECTION 4 (continued)

SECTION 4A (THE HOME)

25. WHAT TYPE OF HOME / ACCOMMODATION DID YOU STAY IN DURING THE TEST PERIOD?

House Flat Caravan Hotel Other.....

26. HOW WELL VENTILATED IS THE HOME / ACCOMMODATION?

Good Moderate Poor

27. IS THIS YOUR NORMAL PLACE OF ACCOMMODATION DURING THE LAST MONTH?.....

28. DID ANYONE SMOKE IN YOUR HOME / ACCOMMODATION DURING THE TWO DAYS PRIOR TO THE TEST PERIOD?.....

29. DID ANYONE SMOKE IN YOUR HOME / ACCOMMODATION DURING THE TEST PERIOD?.....

Spouse/Partner Father Mother Sister Brother Son Daughter. Visitor Other.....

30. FOR HOW MANY HOURS IN YOUR HOME / ACCOMMODATION WERE YOU IN THE SAME ROOM AS SOMEONE SMOKING DURING THE TEST PERIOD?.....

31. HOW DO YOU RATE YOUR EXPOSURE TO TOBACCO IN YOUR HOME / ACCOMMODATION DURING THE TEST PERIOD?

None Very Low Low Moderate High Very High

SECTION 4B (LEISURE)

32. IN WHICH OF THE FOLLOWING DID YOU SPEND LEISURE TIME?

Pub Restaurant Club Cinema Church Sport Education Visiting Shopping Others.....

33. FOR HOW MANY HOURS AT LEISURE WERE YOU IN THE PRESENCE OF SMOKING?.....

34. HOW DO YOU RATE YOUR EXPOSURE TO TOBACCO SMOKE AT LEISURE DURING THE TEST PERIOD?

None Very Low Low Moderate High Very High

2023686484

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Subject no

AIR QUALITY SURVEY QUESTIONNAIRE

SECTION 4 (continued)

SECTION 4C (WORK)** If question 22 = none proceed to Section 4D
(ALL travel should be reported in Section 4D)

35. HOW MANY HOURS AT WORK DID YOU SPEND INSIDE A BUILDING?.....

36. HOW MANY HOURS AT WORK DID YOU SPEND IN THE OPEN AIR?.....

If no work is indoors proceed to Question 41

37. HOW GOOD IS THE VENTILATION IN THE MAIN AREA WHERE YOU WORK INDOORS?

Good Moderate Poor

38. IS THERE AIR CONDITIONING IN THE MAIN AREA WHERE YOU WORK INDOORS?.....

39. IS SMOKING PERMITTED IN THE MAIN AREA WHERE YOU WORK INDOORS?.....

40. IS THERE A SPECIAL AREA SET ASIDE FOR SMOKING?.....

41. FOR HOW MANY HOURS AT WORK DURING THE TEST PERIOD WERE YOU IN THE PRESENCE OF SMOKING?.....

42. HOW DO YOU RATE YOUR EXPOSURE TO TOBACCO SMOKE AT WORK DURING THE TEST PERIOD?

None Very Low Low Moderate High Very High

SECTION 4D (TRAVEL)

43. WHICH FORMS OF TRAVEL DID YOU USE DURING THE TEST PERIOD (DO NOT INCLUDE IF FOR SPORT) ?

Car Bus Train Plane Motorcycle Cycle Walking Other.....

44. FOR HOW MANY OF THESE HOURS OF TRAVEL WERE YOU IN THE PRESENCE OF SMOKING?.....

45. HOW DO YOU RATE YOUR EXPOSURE TO TOBACCO SMOKE WHILE TRAVELLING DURING THE TEST PERIOD?

None Very Low Low Moderate High Very High

2023686485

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Subject no

AIR QUALITY SURVEY QUESTIONNAIRE

SECTION 5

SECTION 5A (SPOUSE SMOKING) If no spouse or partner proceed to Section 5B

46. DOES YOUR SPOUSE/PARTNER SMOKE AT PRESENT?.....

47. HAS YOUR SPOUSE/PARTNER EVER SMOKED SINCE YOU HAVE BEEN TOGETHER?
.....
If spouse/partner is a non-smoker proceed to Section 5B

48. HOW MANY CIGARETTES DOES YOUR SPOUSE/PARTNER NORMALLY SMOKE PER DAY? .....

49. HOW MANY CIGARETTES DOES YOUR SPOUSE/PARTNER NORMALLY SMOKE ANYWHERE IN YOUR PRESENCE PER DAY?.....

50. HOW MANY CIGARETTES DID YOUR SPOUSE/PARTNER SMOKE ANYWHERE IN YOUR PRESENCE DURING THE TEST PERIOD?.....

51. FOR HOW MANY HOURS DID YOUR SPOUSE/PARTNER SMOKE ANYWHERE IN YOUR PRESENCE DURING THE TEST PERIOD?.....

52. DID YOUR SPOUSE/PARTNER SMOKE A PIPE OR CIGARS ANYWHERE IN YOUR PRESENCE DURING THE TEST PERIOD? .....

53. HOW DO YOU RATE YOUR EXPOSURE TO YOUR SPOUSE'S/PARTNER'S TOBACCO SMOKE DURING THE TEST PERIOD?
None Very Low Low Moderate High Very High

SECTION 5B (SMOKING BY OTHER MEMBERS OF HOUSEHOLD)

54. DOES ANY OTHER MEMBER (NOT INCLUDING SPOUSE/PARTNER) OF YOUR HOUSEHOLD SMOKE?.....

If no other smokers in same accommodation proceed to Section 6

55. FOR HOW MANY HOURS DID OTHER MEMBERS (NOT INCLUDING SPOUSE/PARTNER) OF YOUR HOUSEHOLD SMOKE IN YOUR PRESENCE AT YOUR ACCOMMODATION DURING THE TEST PERIOD?.....

56. FOR HOW MANY HOURS DID OTHER MEMBERS (NOT INCLUDING SPOUSE/PARTNER) OF YOUR HOUSEHOLD SMOKE IN YOUR PRESENCE ANY WHERE ELSE DURING THE TEST PERIOD?.....

57. HOW DO YOU RATE YOUR EXPOSURE TO TOBACCO SMOKE FROM OTHER MEMBERS OF YOUR HOUSEHOLD (NOT INCLUDING SPOUSE/PARTNER) DURING THESE HOURS OF SMOKING?

None Very Low Low Moderate High Very High

2023686486

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Subject no

AIR QUALITY SURVEY QUESTIONNAIRE

SECTION 6

58. HOW MANY CIGARETTES DID YOU SMOKE DURING THE TEST PERIOD?.....

59. HOW MANY CIGARETTES DID YOU SMOKE DURING THE LAST WEEK?.....

60. HOW MANY CIGARETTES DID YOU SMOKE DURING THE LAST YEAR?.....

61 WHEN DID YOU LAST SMOKE?.....

62. FOR HOW MANY YEARS HAVE YOU SMOKED DURING YOUR LIFE?.....

63. WHAT WAS THE AVERAGE NUMBER OF CIGARETTES SMOKED PER DAY DURING THESE YEARS OF SMOKING?.....

COMMENTS ABOUT THE TEST PERIOD BY THE SUBJECT.

COMMENTS BY THE INTERVIEWER.

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APPENDIX 3 FIGURE 10

	✓
Address / right volunteer	
Check paperwork / correct pump	
Ask for saliva sample 1¼ to 1½ minutes, must be very moist, place in bag	
Take necklace and monitor / assembly	
Tubing attach to monitor, firmness of fit, if off	
Describe bag and contents	
Note pump reading (counts) / check it	
Switch on pump, note time, check for leaks	
Take off cap to filters	
Tag for security	
Wrap pump up, place in bag, check tubing	
Place on volunteer, explain belt etc	
Pump stops, note approximately when, check tube not pump	
Check pump / tubing if you suspect problem	
Noise at night, with you at all times or	
Dangerous activity	
Problems with entry use	
Letter	
24 to 25 hours, diary and fill out questionnaire	
COLLECTION	
Saliva sample	
Check security tag	
Check for leaks	
Note time switched off	
Check reading	
Questionnaire	

2023686488

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APPENDIX 4

ANALYTICAL METHODS

2023686489

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

SUMMARY

Particles from all sources collected on the personal monitor front filter are estimated gravimetrically. The ETS contribution to these particles is estimated by UV, fluorescence and solanesol measurements on a methanol extract of the filter.

Nicotine and 3-Ethenylpyridine, collected partly by the front filter and mainly by the second acidic filter, are determined by gas chromatography using a nitrogen selective detector.

Saliva samples taken from the subjects are analysed for cotinine content by gas chromatography with mass selective detection.

2023686490

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

OUTLINE PROCEDURE

ANALYSIS OF THE COLLECTED SAMPLES

DISMANTLE THE HOLDER.

WEIGH THE TEFLON FRONT FILTER TO DETERMINE TSP.

EXTRACT THE TEFLON FILTER WITH METHANOL. ANALYSE FOR UVPM, FPM, SOLANESOL, NICOTINE AND 3-ETHENYLPYRIDINE.

ANALYSE THE ACIDIC FILTER FOR NICOTINE AND 3-ETHENYLPYRIDINE.

ANALYSE THE FILTER HOLDER BLANK FOR THE SAME ANALYTES.

ANALYSE THE SALIVA SAMPLES FOR COTININE.

2023686491

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

WEIGHING AND EXTRACTION OF THE FILTERS PRIOR TO ANALYSIS

EQUIPMENT

1. MICROBALANCE

Mettler M3 (6 decimal place) or equivalent. The balance should be mounted on a very stable surface and situated in a temperature controlled laboratory away from strong draughts.

The microbalance should stand on an earthed antistatic mat. During microweighing, the operator should be connected to this mat via an antistatic wrist-band strap. This arrangement eliminates static charge build-up arising from the operator and ambient conditions during microweighing.

2. CHECK-WEIGHT FOR MICROBALANCE

A 20 mg calibration weight was used as a check weight throughout the study. This weight is approximately the same as the weight of a Millipore filter.

3. RADIOACTIVE SEALED SOURCE STATIC ELIMINATOR

BAR-TYPE:	POLONIUM-210 (approximately 148 M Bcq)
CATALOGUE NUMBER:	PDV 1
SUPPLIER:	Amersham International PLC, Buckinghamshire, England

Polonium-210 radioactive static eliminators have a working lifetime of approximately one year.

4. GLASSWARE

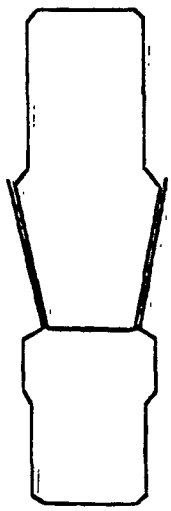
Extraction pots, with ground glass stoppers (See Appendix 4 Figure 1).

Test tubes, 15 mL, with screw top fitting and screw caps with Teflon inner lining.

2023686492

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

APPENDIX 4 FIGURE 1



34/35 GROUND GLASS STOPPER

GROUND GLASS JOINT

27 mm ID VESSEL TO ACCOMMODATE FILTER PARTS

EXTRACTION POT

2023686493

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

REAGENTS

Methanol: HPLC grade, 99.9% minimum (Romil Super Purity or equivalent)

Di-isopropyl ether (DIPE): HPLC grade, 99.9% minimum (Romil Super Purity or equivalent)

DIPE solvent. Containing (1) 0.1 mL/litre triethylamine
(2) 2.0 mg/litre N-ethylnornicotine.

Solanesol: (Sigma), 90%+. Purity checked against purified solanesol (98%+)

Nicotine: Double distilled 99%+

3 Ethenylpyridine: Double distilled 98%+ (containing 0.5% hydroquinone as a stabiliser)

N-Ethylnornicotine: Double distilled 99%+

Cotinine: (Lancaster Synthesis) 98%

N-Ethylnorcotinine 98%

Scopoletin: (Aldrich) 95%

2,2',4,4'-Tetrahydroxybenzophenone: (Aldrich) 97%

Triethylamine: (BDH) 99.5%

Dichloromethane: (BDH) GC analysis grade

2023686494

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

DISMANTLE THE HOLDER

Break the security tag and unscrew the clamping cover (see Appendix 4 Figure 2).

Carefully remove the filter holder entrance plate while keeping the holder upright to ensure that the filters stay in place.

WEIGH THE TEFLON FRONT FILTER TO DETERMINE TSP

Carefully remove the Millipore filter from the holder with clean stainless steel tweezers.

Ensure the balance has gone through its daily calibration check and that the check-weight is within 1 μg of the last check and 2 μg of the expected value determined at the start of the project.

Weigh the filter by the same procedure as used when the filter was weighed before the sampling period.

Calculate the weight of particulate matter collected on the filter from the difference in weight before sampling and after sampling.

Calculate the weight of particulate matter in μg collected per cubic metre.

TSP=(W2-W1)*1000/VA μg/m3

Where:

W1=weight of filter before sampling in μg

W2=weight of filter after sampling in μg

VA=volume of air sample collected in litres

EXTRACT THE TEFLON FRONT FILTER AND TEFLON SEAL WITH METHANOL FOR SUBSEQUENT ANALYSIS FOR UVPM, FPM, SOLANESOL, NICOTINE AND 3-ETHENYLPYRIDINE

2023686495

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

EXTRACT THE ACID FILTER FOR NICOTINE AND 3-ETHENYLPYRIDINE ANALYSIS

Remove the first Teflon spacer, the acid-treated Pallflex filter and the second Teflon spacer from the filter holder using clean stainless steel tweezers. Transfer these to an extraction pot and add 1.0 mL DIPE (containing internal standard and triethylamine) followed by 4 mL 5N sodium hydroxide. Stopper the extraction pot and shake gently for 30 minutes.

Transfer as much of the liquid as possible to a screw topped 15 mL test tube and cap the tube with a Teflon lined cap.

Allow the phases to separate and then transfer about 0.5 mL of the upper (DIPE) layer to an autosampler vial and cap the vial. Take care not to transfer any of the aqueous phase.

This vial will be used for measurement of nicotine and 3-Ethenylpyridine collected on the second filter. Store the vial in the freezer (-20°C) until ready for use. (Referred to as Vial C).

Place the Millipore filter, the Teflon seal, the metal 'O' ring and the metal grid (See Figure 2) in a clean extraction pot and seal with a glass stopper.

Add 5.0 mL of methanol. Stopper the extraction pot and shake gently for 30 minutes. Pipette 1.0 mL of the methanol into a screw topped 15 mL test tube. Add 1.0 mL of DIPE (containing internal standard and triethylamine) and 4.0 mL of 5N sodium hydroxide. Cap the tube with a Teflon lined cap. Mix thoroughly for 10 minutes using a vortex mixer. Allow the phases to separate and then transfer at least 0.5 mL of the upper (DIPE) layer to an autosampler vial and cap the vial. Take care not to transfer any of the aqueous phase.

This vial will be used for measurement of any nicotine and 3-Ethenylpyridine collected on the first filter. Store the vial in the freezer (-20°C) until ready for use. (Referred to as Vial A).

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Fill a 2 mL autosampler vial with some of the remaining methanol extract and cap the vial. This vial will be used for measurement of UVPM, FPM and solanesol. Store the vial in the freezer (-20°C) until ready for use. (Referred to as Vial B).

Transfer the remaining methanol extract to an autosampler vial for backup purposes. Store this vial in a freezer (-20°C) until required for use.

ANALYSE THE FILTER HOLDER BLANK FOR THE SAME ANALYTES

Dismantle the blank filter holder and carry out the same weighing and extractions as for the sample filter holders.

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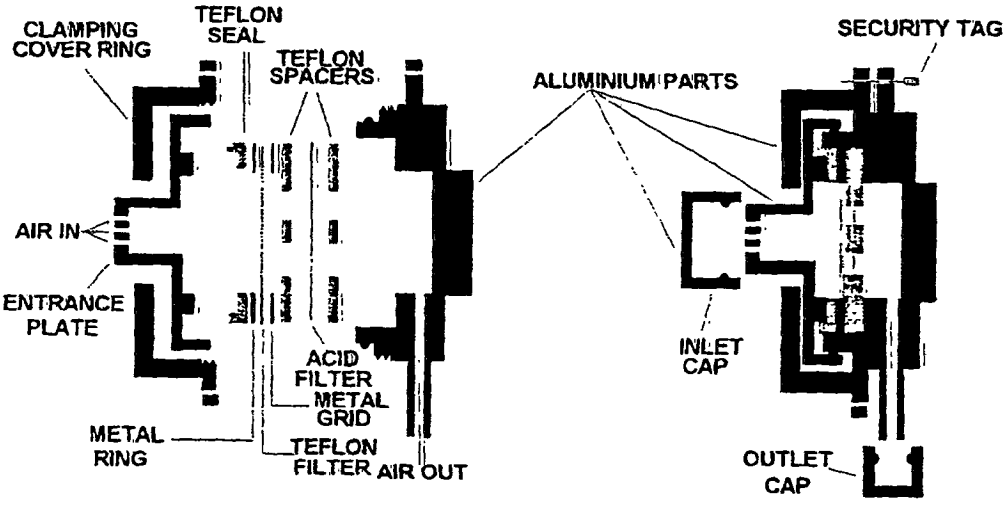
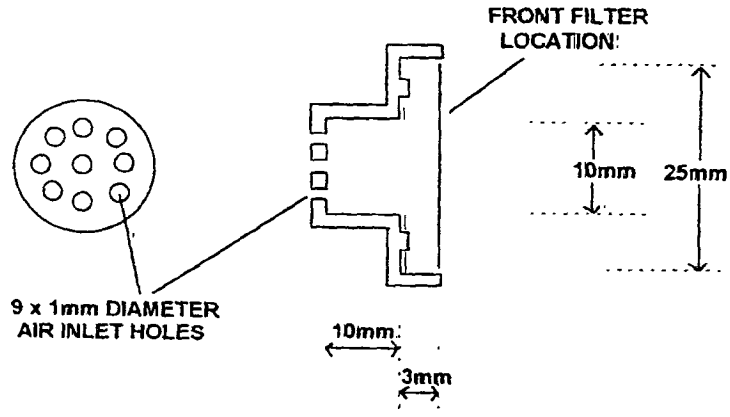
APPENDIX 4 FIGURE 2



FILTER HOLDER APART AND ASSEMBLED



ENTRANCE PLATE DIMENSIONS

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

ESTIMATION OF UVPM AND FPM

PRINCIPLE

Particulate matter collected on a Millipore Teflon filter is extracted with methanol. UV and fluorescence measurements are made on this extract and these are compared to calibrations made using surrogate standards for ETS particles.

The calibration of surrogate standards against ETS has been established in prior experiments using ETS generated in a Model Room using the same master calibration solutions. This enables the UV and Fluorescence measurements to be converted to a weight of ETS particles.

EQUIPMENT

HPLC Pump capable of pumping methanol at 1.0 mL/min.

UV detector set at 325 nm, cell volume 14 μL, path length 10 mm.

Fluorescence detector with Excitation 300 nm and Emission 420 nm, cell volume 16 μL, path length 10 mm.

Thermostatted column oven set at 30°C

Delay tube / restrictor: Empty stainless steel tube, 4 m long, 0.33 mm ID

Frit filter

Loop injector with 50 μL loop.

The equipment is set up as a column-less HPLC system with the fluorescence detector and UV and detector used in series.

REAGENTS

Methanol: HPLC grade, 99.9% minimum (Romil Super Purity or equivalent)

Scopoletin: (Aldrich) 95%

2,2',4,4'-Tetrahydroxybenzophenone: (Aldrich) 97%

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

CALIBRATION

1. UVPM

Prepare (by dilution from a stronger solution) a master solution containing 12.5 mg of 2,2',4,4'-Tetrahydroxybenzophenone (THBP) in 2.5 litres of methanol (ie 5 μg/mL).

Store this solution in a 2.5 litre amber Winchester reagent bottle used previously to store methanol.

This solution is stable for at least six months when stored in a refrigerator.

Prepare calibration solutions by dilution of the master solution with methanol as follows:

CONCENTRATION μg/mL	DILUTION OF MASTER	EQUIVALENT UVPM μg/mL
2.5	50 mL to 100 mL	15.25
1.0	20 mL to 100 mL	6.1
0.5	10 mL to 100 mL	3.05
0.25	5 mL to 100 mL	1.53
0.10	2 mL to 100 mL	0.61
0.05	1 mL to 100 mL	0.31
0.00	0 mL to 100 mL	0

These calibration solutions cover a range equivalent to 0 - 380 μg/m^3 of ETS particles. The 0.05 μg/mL calibration point corresponds to 7.6 μg/m^3 ETS particles.

These diluted calibration solutions should be prepared fresh every week and stored in the refrigerator.

2. FPM

Prepare (by dilution from a stronger solution) a master solution containing 2.5 mg scopoletin in 2.5 litres of methanol (ie 1 μg/mL).

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Store this solution in a 2.5 litre amber Winchester reagent bottle used previously to store methanol.

This solution is stable for at least six months when stored in a refrigerator.

Prepare calibration solutions by dilution of the master solution with methanol as follows:

CONCENTRATION µg/mL	DILUTION OF MASTER	EQUIVALENT UVPM µg/mL
0.50	50 mL to 100 mL	11.25
0.25	25 mL to 100 mL	5.63
0.10	10 mL to 100 mL	2.25
0.050	5 mL to 100 mL	1.13
0.020	2 mL to 100 mL	0.45
0.010	1 mL to 100 mL	0.23
0.00	0 mL to 100 mL	0

These calibration solutions cover a range equivalent to 0 to 281 $\mu g/m^3$ of ETS particles. The calibration point 0.01 µg/mL corresponds to 5.6 $\mu g/m^3$ ETS particles.

These diluted calibration solutions should be prepared fresh every week and stored in the refrigerator.

Fill autosampler vials with each of the THBP and scopoletin calibration solutions.

Make duplicate injections of each calibration solution into the combined UVPM/FPM system using the loop injector. Measure the peak area of the UV absorbance peak using an integrator.

Prepare a calibration graph of UV Absorbance Peak Area against UVPM concentration (as calculated from the THBP concentration).

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Prepare a calibration graph of Fluorescence Emission Peak Area against FPM Concentration (as calculated from the scopoletin concentration).

METHOD

Make duplicate injections of the methanol extract of the particulate matter (collected on the Millipore Teflon filter) from its autosampler vial (Referred to as Vial B) into the UVPM/FPM system using the loop injector.

Determine the UV Absorbance Peak Area and the Fluorescence Emission Peak Area.

CALCULATION

By reference to the calibration graphs (or the equation of best fit), determine the UVPM concentration and FPM concentration of the sample solution in μg/mL.

Calculate the quantities of UVPM and FPM per cubic metre of air sampled as follows:

UVPM=U*VM*1000/VA μg/m3

FPM=F*VM*1000/VA μg/m3

Where:

U=UVPM concentration in methanol extract, in μg/mL

F=FPM concentration in methanol extract, in μg/mL

VM=volume of methanol used to extract the Millipore filter, in mL

VA=volume of air sample collected, in litres

Correct the results for values obtained from the blank.

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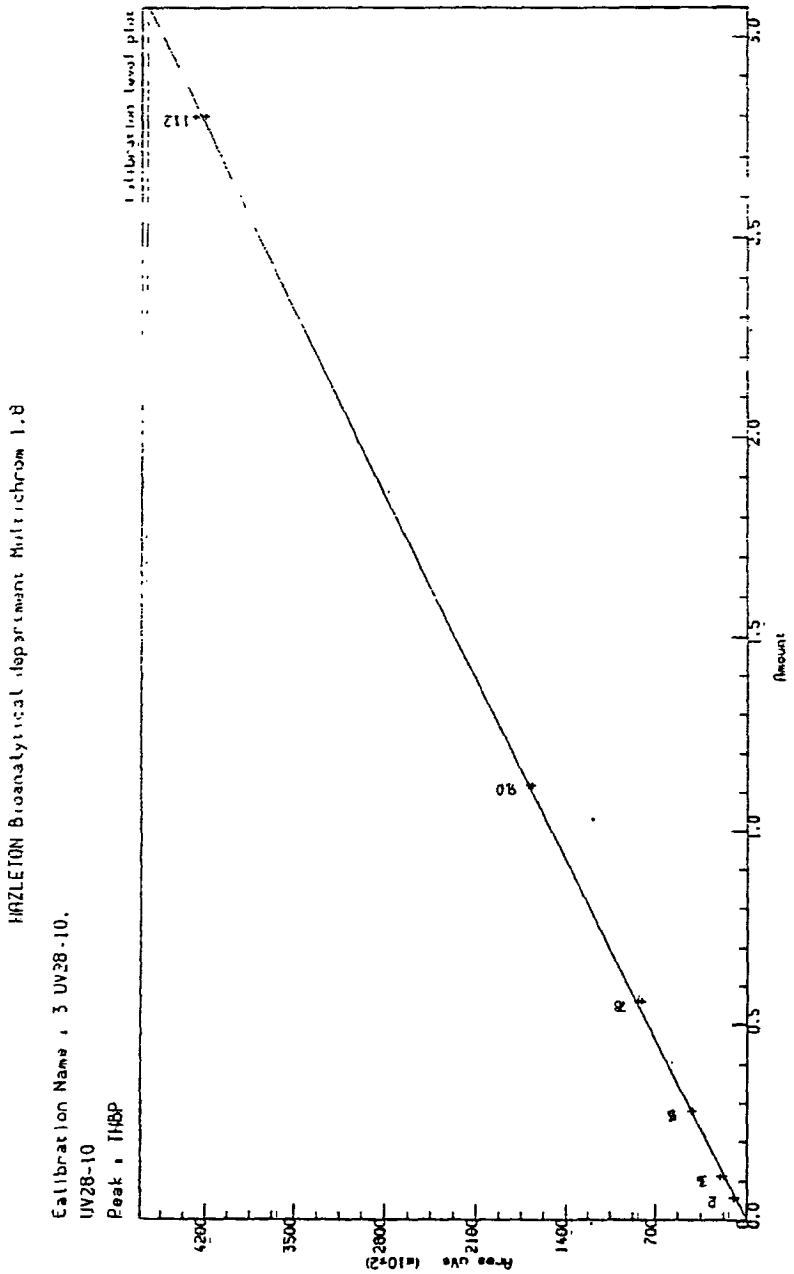
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Typical UVPM calibration plot
(using THBP standard)



JMW 26/5/92

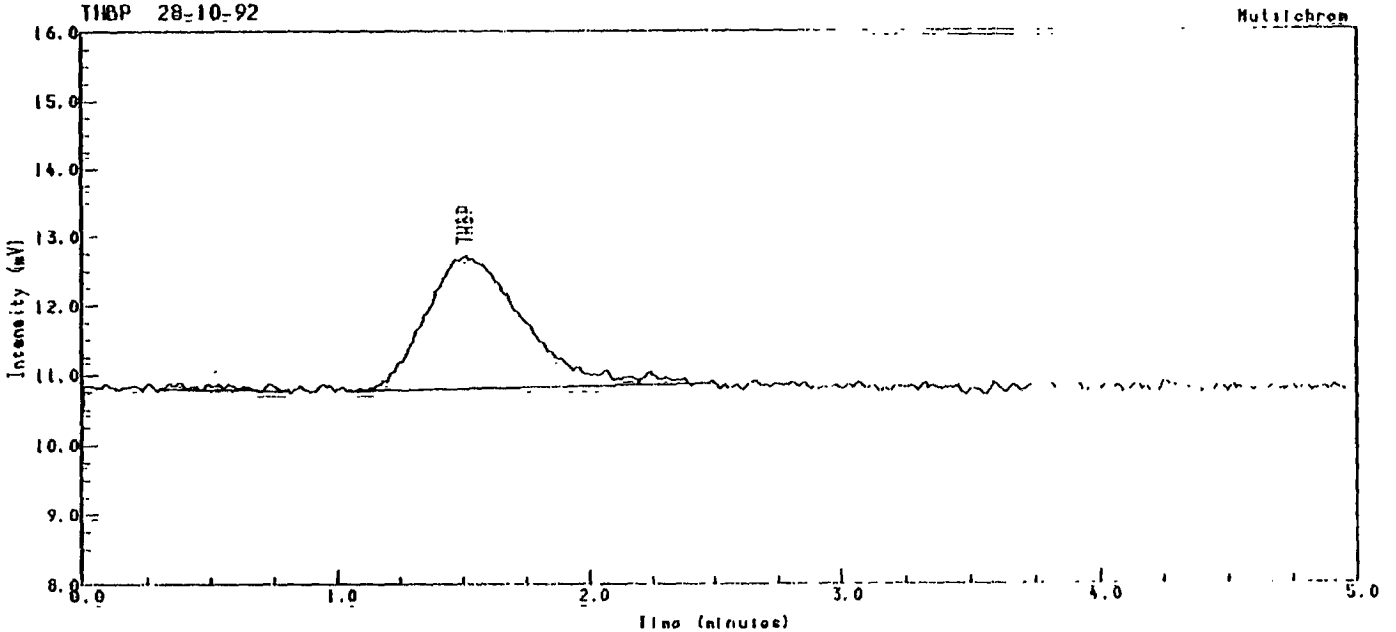
2023686503

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Typical sample UV absorbance for UVPM

HAZLETON Bioanalytical department Multichrom 1.8

Analysis Name : [JM12_64] 3 UV28-10,28,1.
28-10/118-06 Amount : 1.000
THBP 28-10-92



Instrument :
Channel Title : Channel #3
Lims ID :
Acquired on 30-OCT-1992 at 21:51
Reported on 26-NOV-1992 at 14:14

Method : UV28-10
Calibration : UV28-10
Run Sequence : UV28-10

JM

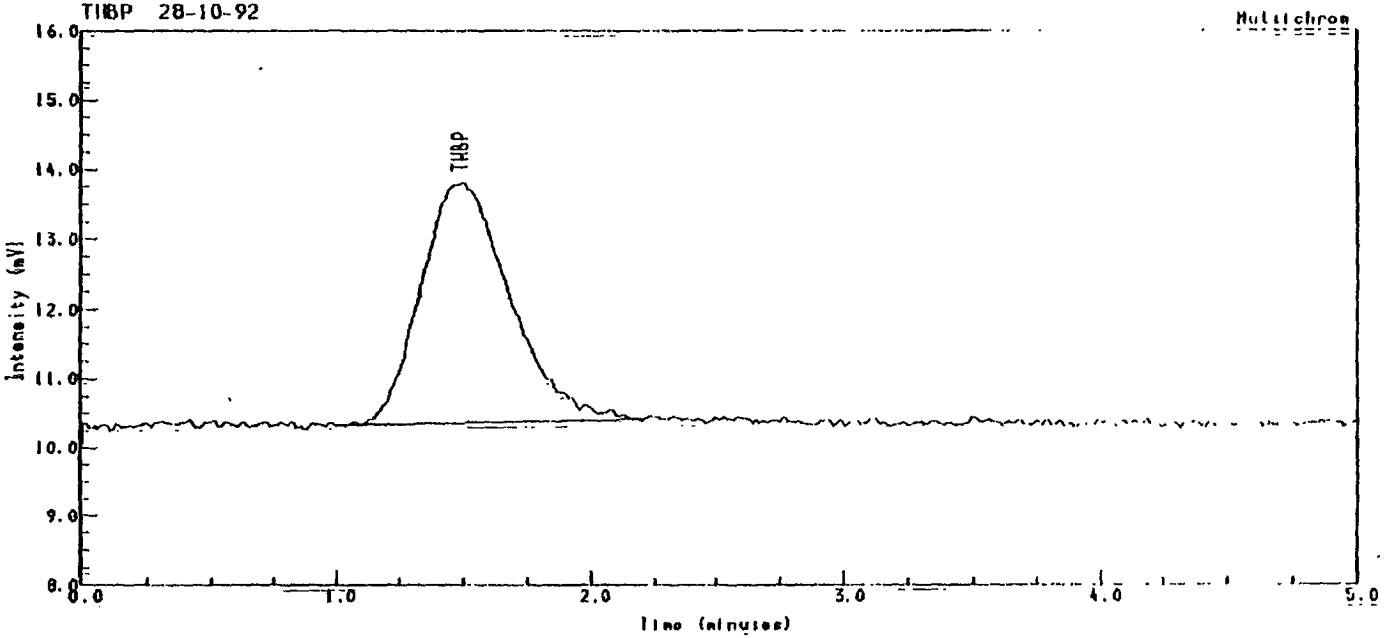
2023686504

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Typical standard UV absorbance for UVPM
(0.5 µg/mL THBP)

WAZLETON Bioanalytical department Multichrom 1.0

Analysis Name : [JM12_64] 3 UV28-10.22.1.
UCal 0.50 Amount : 1.000
THBP 28-10-92



Instrument :
Channel Title : Channel #3
Lims ID :
Acquired on 30-OCT-1992 at 21:01
Reported on 26-NOV-1992 at 14:14

Method : UV28-10
Calibration : UV28-10
Run Sequence : UV28-10

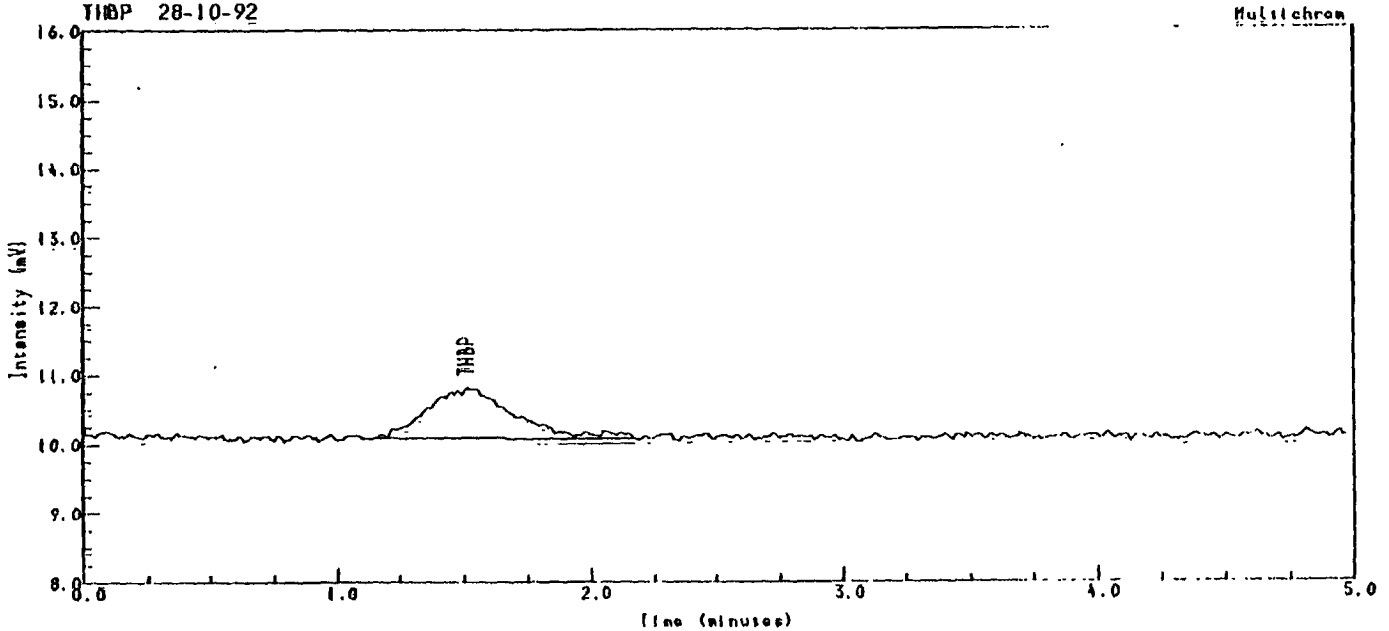
JML

2023686505

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

HAZLETON Bioanalytical department Multichrom 1.8

Analysis Name : [JM12_64] 3 UV28-10,17.1.
UCal 0.10 Amount : 1.000
THBP 28-10-92



Instrument :
Channel Title : Channel #3
Lims ID :
Acquired on 30-OCT-1992 at 20:21
Reported on 26-NOV-1992 at 14:13 P.M.

Method : UV28-10
Calibration : UV28-10
Run Sequence : UV28-10

JM

2023686506

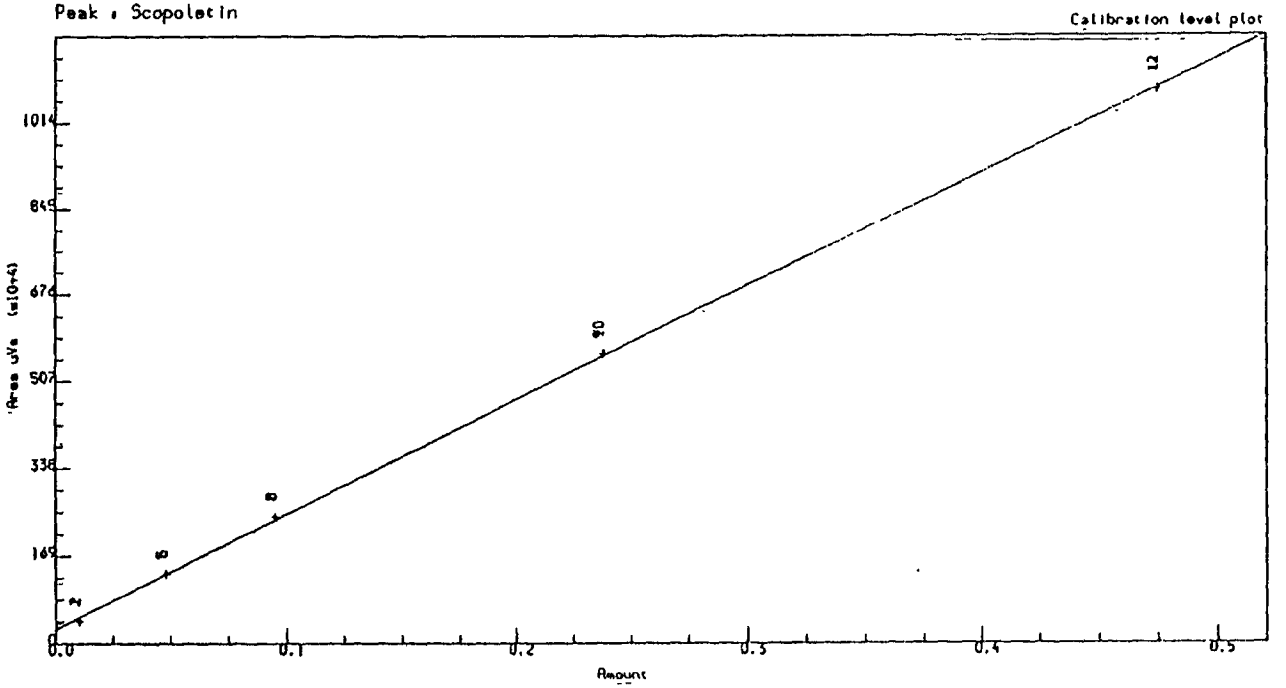
Typical standard UV absorbance for UVPM
(0.1 µg/mL THBP)

HUK Study no 12/64

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

HAZLETON Bioanalytical department Multichrom 1.8

Calibration Name : 1 FS-11.
FS-11
Peak : Scopoletin



Constant : 2.81482E+5
1st degree : 2.21498E+7

RU

FAP 26.11.92

Curve fit : Linear
Correlation coefficient : 0.99992
Standard error : 5.44278E+4

Reported on 23-NOV-1992 at 15:24

Typical FPM calibration plot
(using Scopoletin as standard)

HUK Study no. 12/64

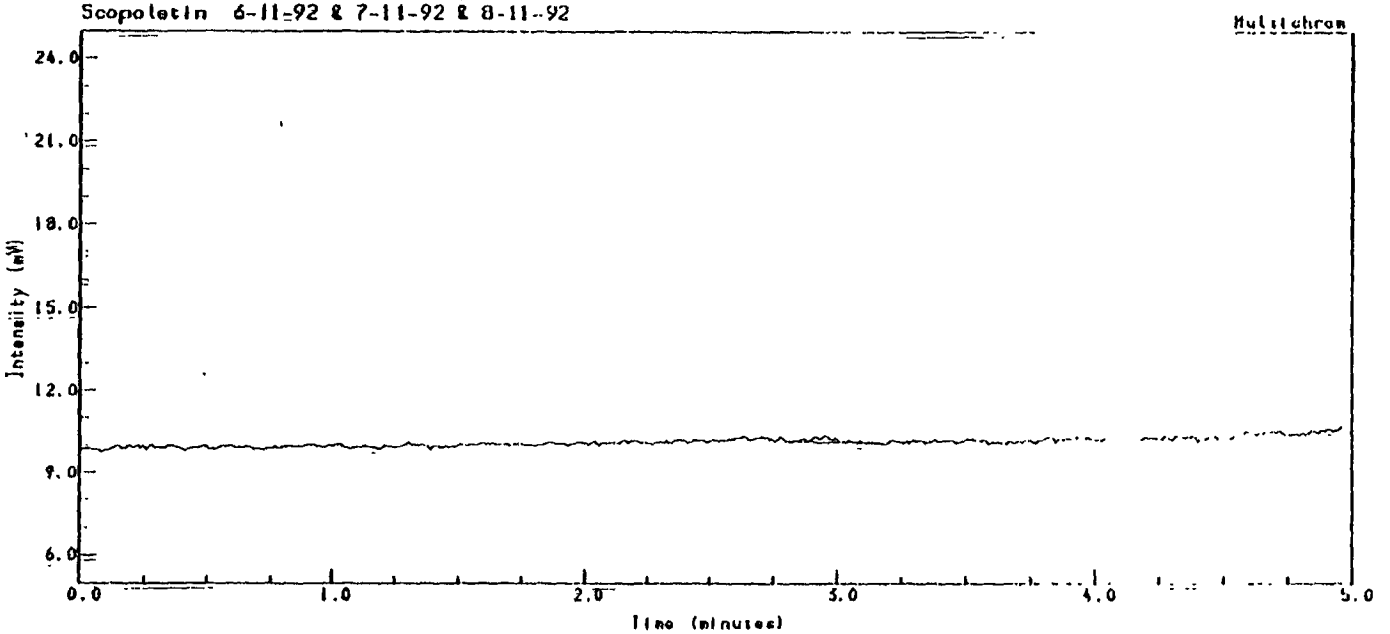
2023686507

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Typical standard calibration fluorescence response (blank)

HAZLETON Bioanalytical department Multichrom 1.8

Analysis Name : [JM12_64] 1 F5-11,1,1.
Cal 0 (MeOH) Amount : 1.000
Scopoletin 6-11-92 & 7-11-92 & 8-11-92



Instrument :
Channel Title : Channel 1
Lims ID :
Acquired on 10-NOV-1992 at 20:53
Reported on 23-NOV-1992 at 15:48

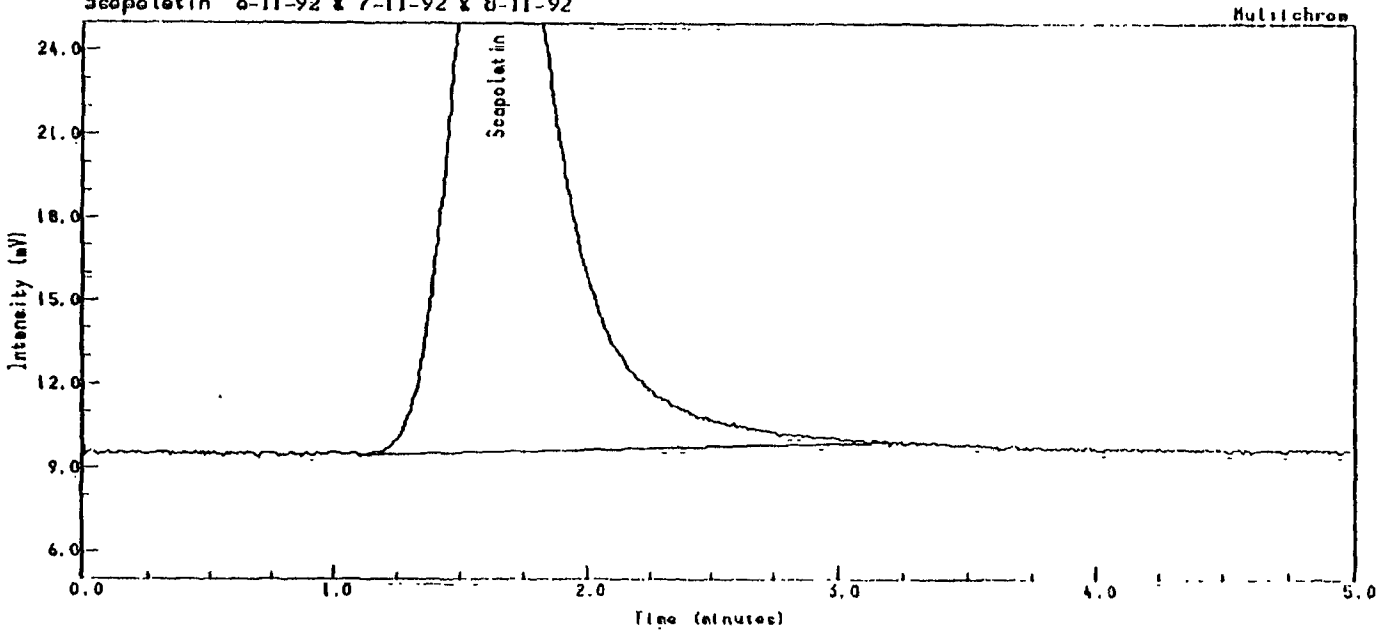
Method : F5-11
Calibration : F5-11
Run Sequence : F5-11

20236865O8

Typical sample fluorescence response

HAZLETON Bioanalytical department Multichrom 1.8

Analysis Name : [JH12_64] 1 F5-11,44,1.
07-11/169-14 , Amount : 1.000
Scopoletin 6-11-92 & 7-11-92 & 8-11-92



Instrument :
Channel Title : Channel 1
Lims ID :
Acquired on 11-NOV-1992 at 02:42
Reported on 23-NOV-1992 at 15:55

Method : F5-11
Calibration : F5-11
Run Sequence : F5-11

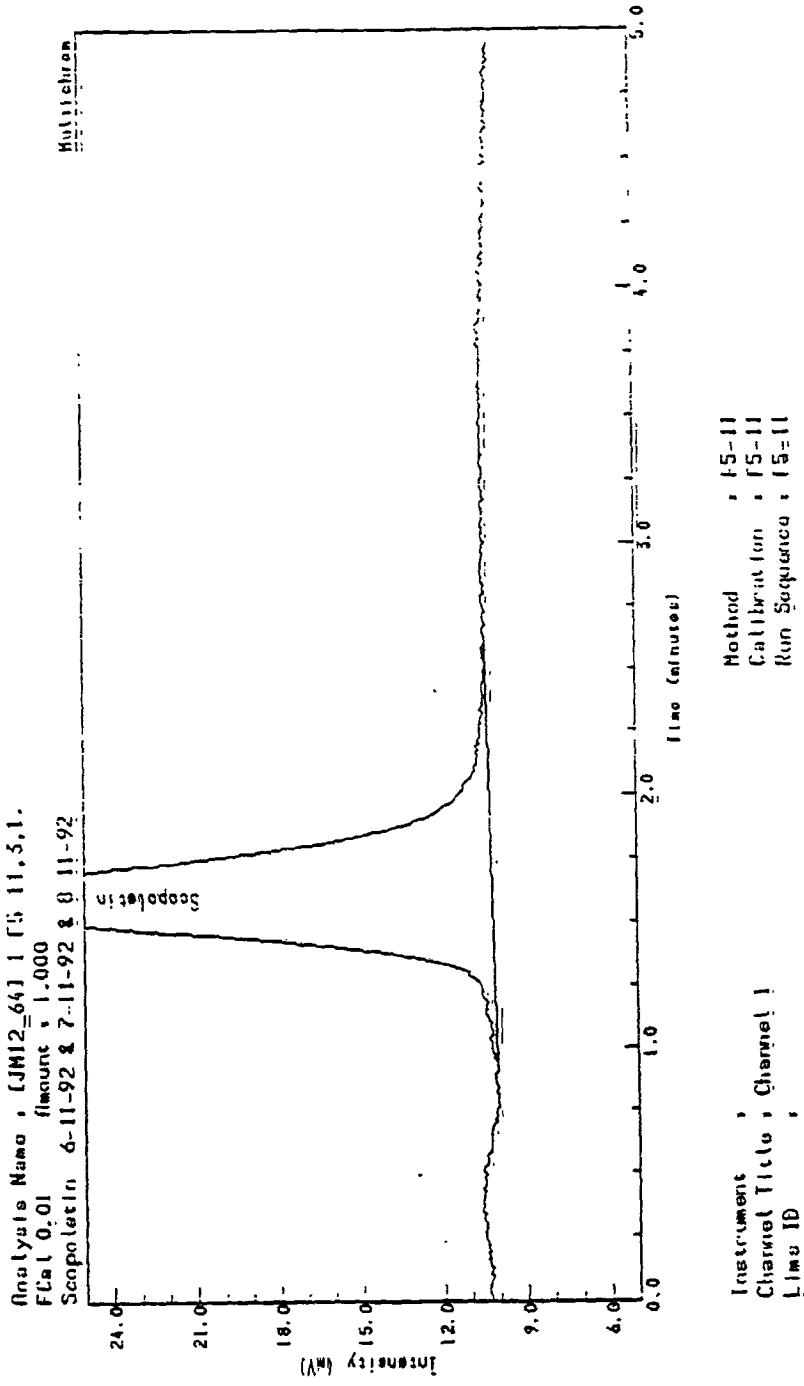
Q.C

AMP

20236865O9

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Typical standard calibration fluorescence response
(0.01 µg/mL)



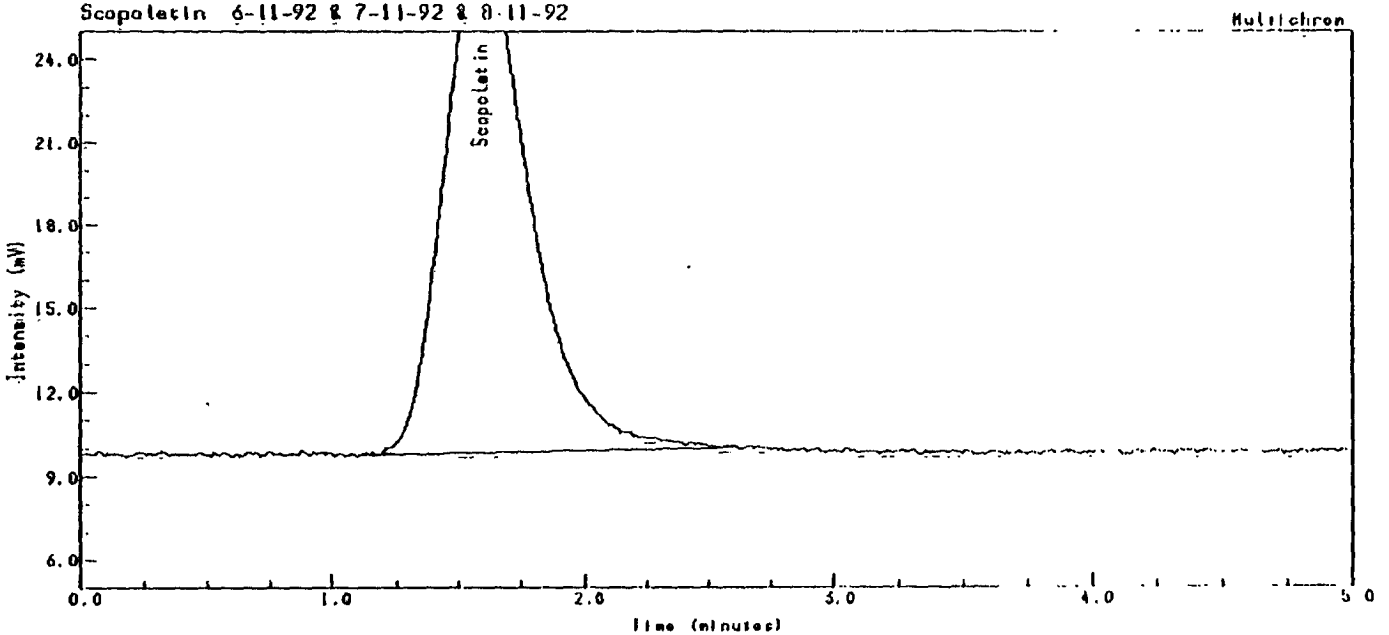
2023686510

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Typical standard calibration fluorescence response
(0.02 µg/mL)

HAZLETON Bioanalytical department Multichrom 1.8

Analysis Name : [JM12_64] 1 FS-11.6.1.
FCal 0.02 Amount : 1.000
Scopoletin 6-11-92 & 7-11-92 & 8-11-92



Instrument :
Channel Title : Channel 1
Lims ID :
Acquired on 10-NOV-1992 at 21:35
Reported on 23-NOV-1992 at 15:49

Method : FS-11
Calibration : FS-11
Run Sequence : FS-11

20236851

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

DETERMINATION OF SOLANESOL CONTENT AND SOLANESOL-BASED ETS PARTICLES (SPM)

PRINCIPLE

Particulate matter collected on a Millipore Teflon filter is extracted with methanol.

The Solanesol content of this extract is measured by HPLC.

Solanesol-based ETS particulate matter is calculated using a pre-determined factor which is calculated from the solanesol content of ETS particles generated in a Model Room.

EQUIPMENT

HPLC Pump capable of pumping methanol at 2.0 mL/min.

UV detector set at 210 nm, cell volume 8 μL, path length 10 mm.

Thermostatted column oven set at 30°C

Guard column:(Waters) Guard-Pak C18

Analytical column: Such as 15 cm (or 25 cm) Spherisorb ODS 2, 5 micron

Loop injector with 200 μL loop.

REAGENTS

Methanol, HPLC grade, 99.9% minimum(Romil Super Purity or equivalent)

Solanesol: (Sigma), (90%+) further purified by sponsor to 98%+.

CALIBRATION

Prepare (by dilution from a stronger solution) a master solution containing 2.5 mg of solanesol in 2.5 litres of methanol (ie 1 μg/mL).

Store this solution in a 2.5 litre amber Winchester reagent bottle used previously to store methanol.

This solution is stable for at least six months when stored in a refrigerator.

2023686512

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Prepare calibration solutions by dilution of the master solution with methanol as follows:

CONCENTRATION µg/mL	DILUTION OF MASTER	EQUIVALENT UVPM µg/mL
0.5	50 mL to 100 mL	19.25
0.25	25 mL to 100 mL	9.63
0.10	10 mL to 100 mL	3.85
0.050	5 mL to 100 mL	1.93
0.020	2 mL to 100 mL	0.77
0.010	1 mL to 100 mL	0.39
0.005	50 mL 0.01 µg/mL to 100 mL	0.19
0.00	0 mL to 100 mL	0

These calibration solutions cover a range of 0 to 480 $\mu g/m^3$ of SPM. The calibration point of 0.005 µg/mL corresponds to 4.8 $\mu g/m^3$.

These diluted calibration solutions should be prepared fresh every week and stored in the refrigerator.

Fill an autosampler vial with each of the solanesol calibration solutions.

Make duplicate injections of each calibration solution into the HPLC system using the loop injector.

Allow the separation to continue to 1.5 times the solanesol retention time in order to elute later peaks.

Measure the peak area of the UV absorbance peak corresponding to solanesol using an integrator. For the lower level calibrations manual peak height measurements are more reliable than integrator peak areas.

Prepare a calibration graph of Peak Area against solanesol concentration.

2023686513

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

METHOD

Make duplicate injections of the methanol extract of the particulate matter (collected on the Millipore Teflon filter) from its autosampler vial (referred to as vial B) into the HPLC system using the loop injector.

Determine the Peak Area/Peak Height corresponding to solanesol using an integrator/ruler.

CALCULATION

By reference to the calibration graph (or the equation of best fit), determine the solanesol concentration of the sample solution in μg/mL.

Calculate the quantity of solanesol per cubic metre of air sampled as follows:
Solanesol=S*VM*1000/VA μg/m3

Calculate the quantity of SPM per cubic metre of air sampled as follows:
SPM=Solanesol*FS μg/m3
Where:
S=solanesol concentration in methanol extract, in μg/mL
VM=volume of methanol used to extract the Millipore filter, in mL
VA=volume of air sample collected, in litres.
FS=Factor to convert solanesol to SPM

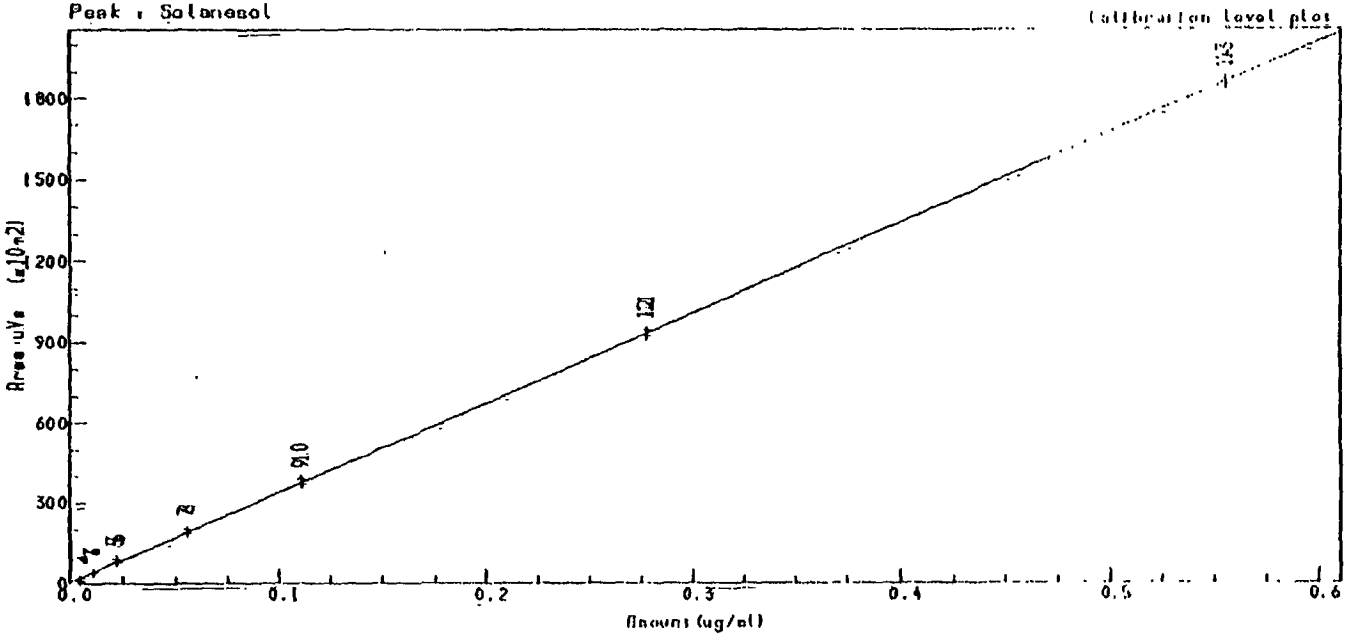
Correct the results for values obtained from the blank.

2023686514

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

HAZLETON Bioanalytical department Multichrom 1.0

Calibration Name : 4 S1-11.
S1-11
Peak : Solanesol



Constant : 4.89181E+2
1st degree : 3.34367E+5

Curve fit : Linear
Correlation coefficient : 0.999881
Standard error : 1.031401E+3

Reported on 3-DEC-1992 at 13:09

R.J.

2023686515

Solanesol calibration plot

- 202 -

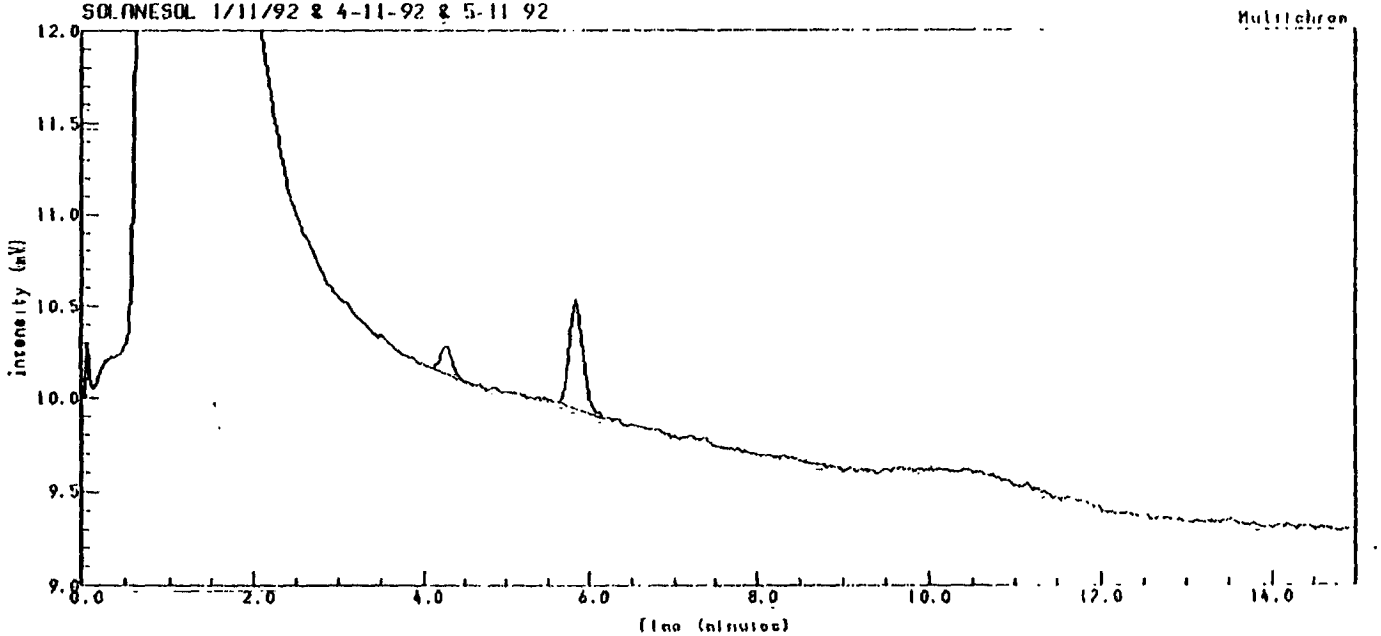
HUK Study no 12/64

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Typical sample chromatogram
(solanesol absent)

HAZLETON Bioanalytical department Multichrom 1.8

Analysis Name : [JM12_64] 4 S1-11.20.1.
01-11/141-15 Amount : 1.000
SOLANESOL 1/11/92 & 4-11-92 & 5-11 92



Instrument :
Channel Title : Channel #4
Lims ID :
Acquired on 9-NOV-1992 at 00:17
Reported on 3-DEC-1992 at 13:19

Method : S1-11
Calibration : S1-11
Run Sequence : S1-11

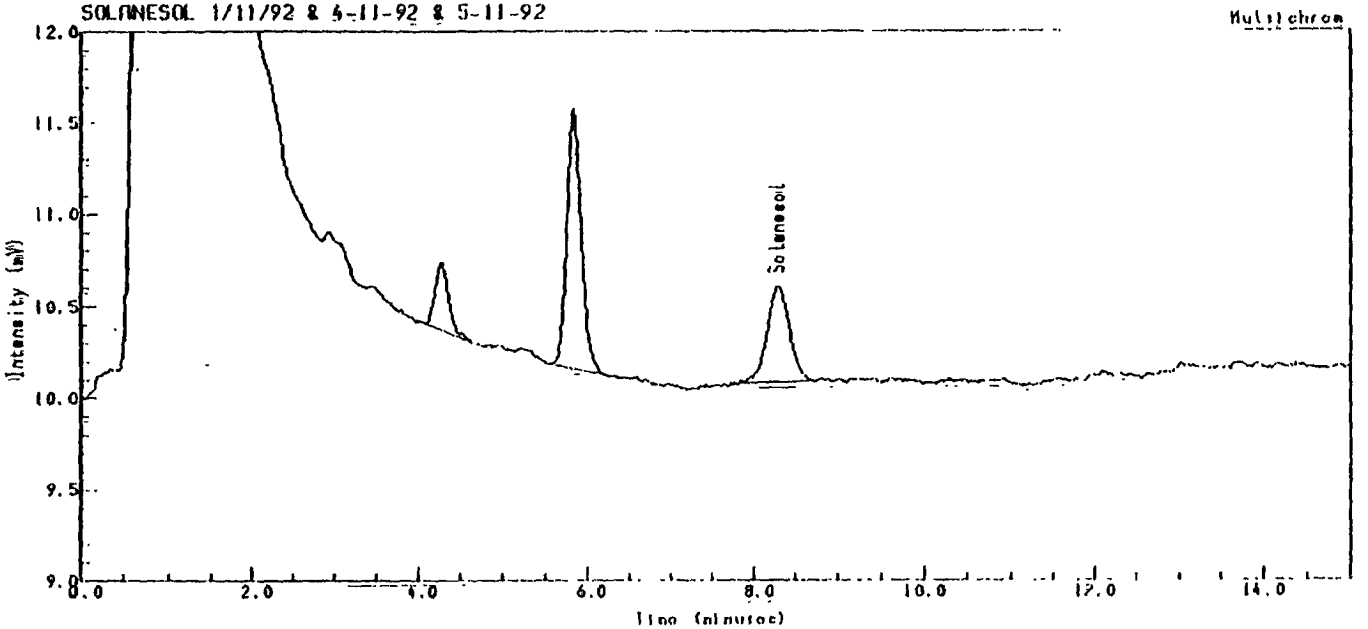
2023686516

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Typical sample chromatogram
(solanesol present)

HAZLETON Bioanalytical department Multichrom 1.0

Analysis Name : [JM12_64] 4 S1-11,24,1.
01-11/143-19 Amount : 1.000
SOLANESOL 1/11/92 & 4-11-92 & 5-11-92



Instrument :
Channel Title : Channel #4
Lims ID :
Acquired on 9-NOV-1992 at 01:32
Reported on 3-DEC-1992 at 13:19

Method : S1-11
Calibration : S1-11
Run Sequence : S1-11

2023686517

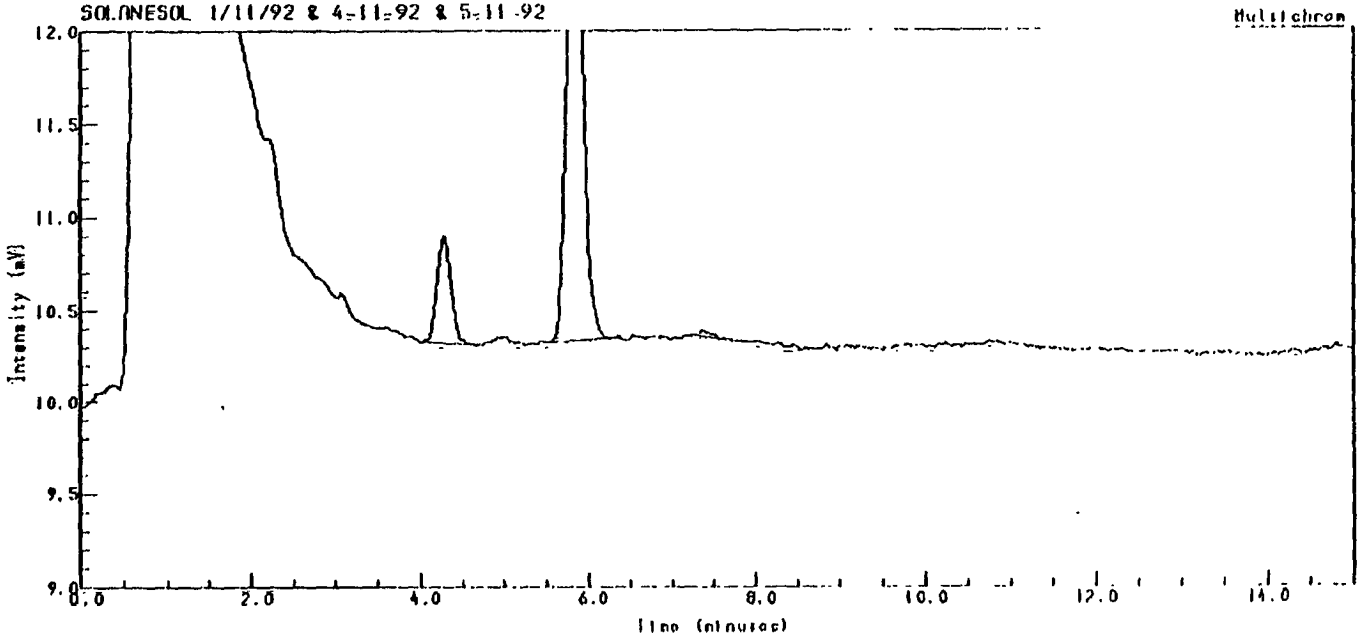
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

HUK Study no. 12/64

Typical control blank

HAZLETON Bioanalytical department Multichrom 1.0

Analysis Name : [JM12_64] 4 S1-11,28,1.
01-11/BLK-21 Amount : 1.000
SOLANESOL 1/11/92 & 4-11-92 & 5-11-92



Instrument :
Channel Title : Channel #4
Lims ID :
Acquired on 9-NOV-1992 at 02:49
Reported on 3-DEC-1992 at 13:20

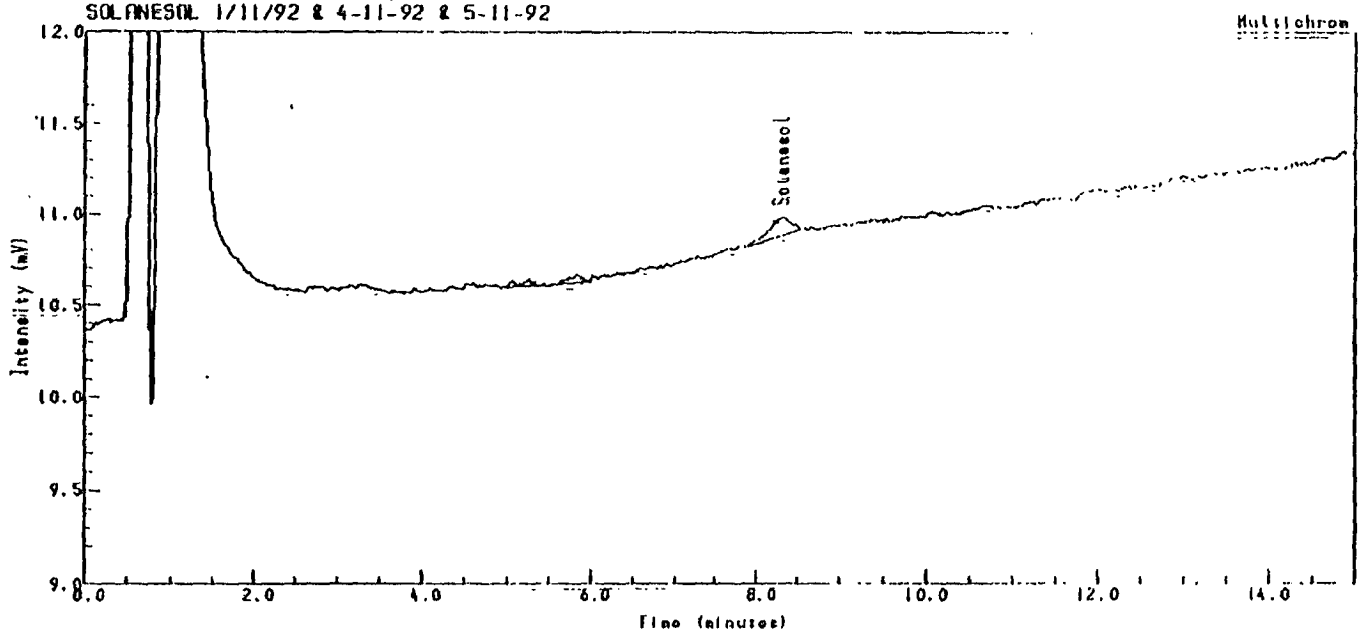
Method : S1-11
Calibration : S1-11
Run Sequence : S1-11

2023686518

Typical standard calibration chromatogram
(0.05 µg/mL)

HAZELTON Bioanalytical department Multichrom 1.8

Analysis Name : [JM12_64] 4 S1-11,3,1.
Cal 0.005 Amount : 1.000
SOLANESOL 1/11/92 & 4-11-92 & 5-11-92



Instrument :
Channel Title : Channel #4
Lims ID :
Acquired on 8-NOV-1992 at 18:56
Reported on 3-DEC-1992 at 13:16

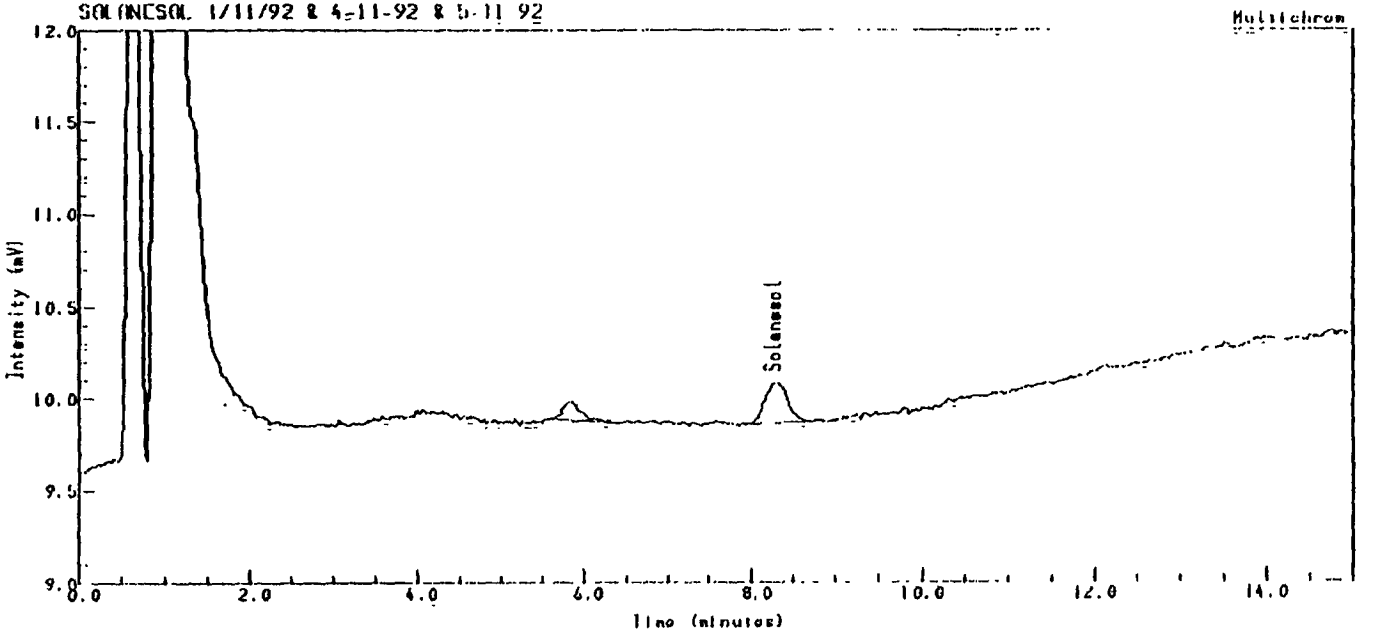
Method : S1 11
Calibration : S1-11
Run Sequence : S1-11

2023686519

Typical standard calibration chromatogram (0.01 µg/mL)

HAZLETON Bioanalytical department Multichrom 1.0

Analysis Name : [JM12_641 4 S1 11.5.1.
Cal 0.010 Amount : 1.000
SOLANCSOL 1/11/92 & 4-11-92 & 5-11 92



Instrument :
Channel Title : Channel #4
Lims ID :
Acquired on 8-NOV-1992 at 19.34
Reported on 3-DEC-1992 at 13.16

Method : S1-11
Calibration : S1-11
Run Sequence : S1-11

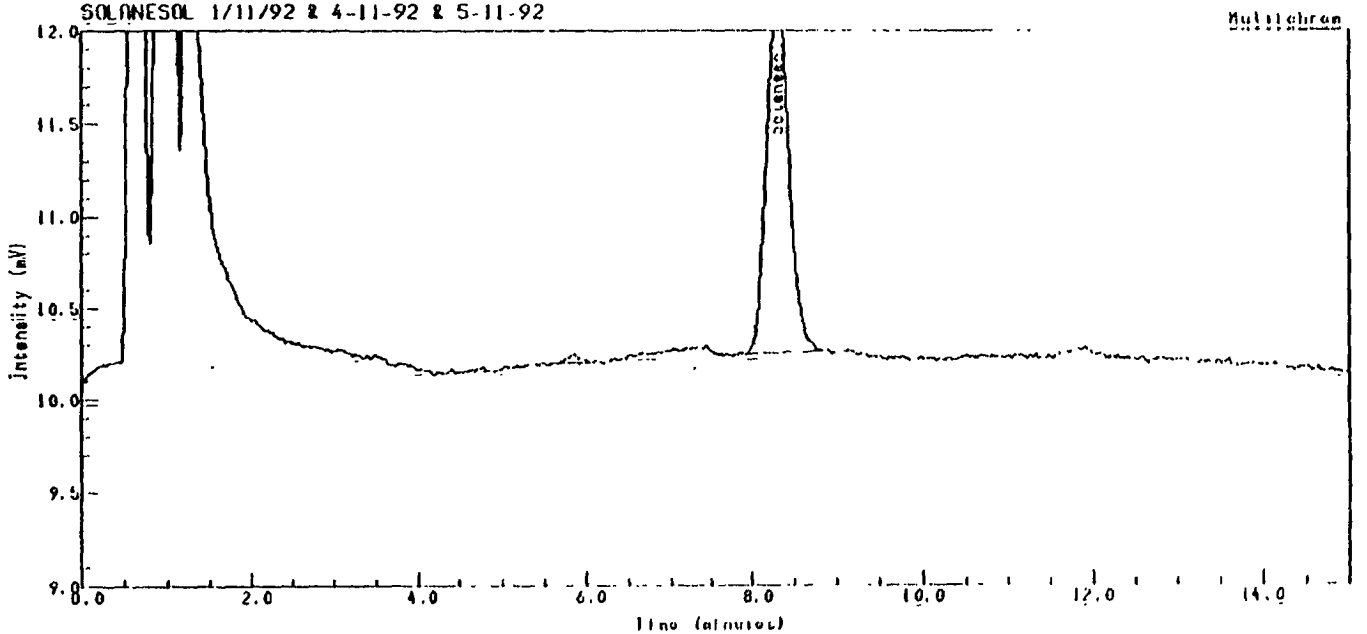
2023686520

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Typical standard calibration chromatogram
(0.10 µg/mL)

HOECHST Bioanalytical department Multichrom 1.0

Analysis Name : [JM12_64] 4 SI-11,11,1.
Cal 0.100 Amount : 1.000
SOLANESOL 1/11/92 & 4-11-92 & 5-11-92



Instrument :
Channel Title : Channel #4
Time ID :
Acquired on 8-NOV-1992 at 21:27
Reported on 3-DEC-1992 at 13:17

Method : SI-11
Calibration : SI-11
Run Sequence : SI-11

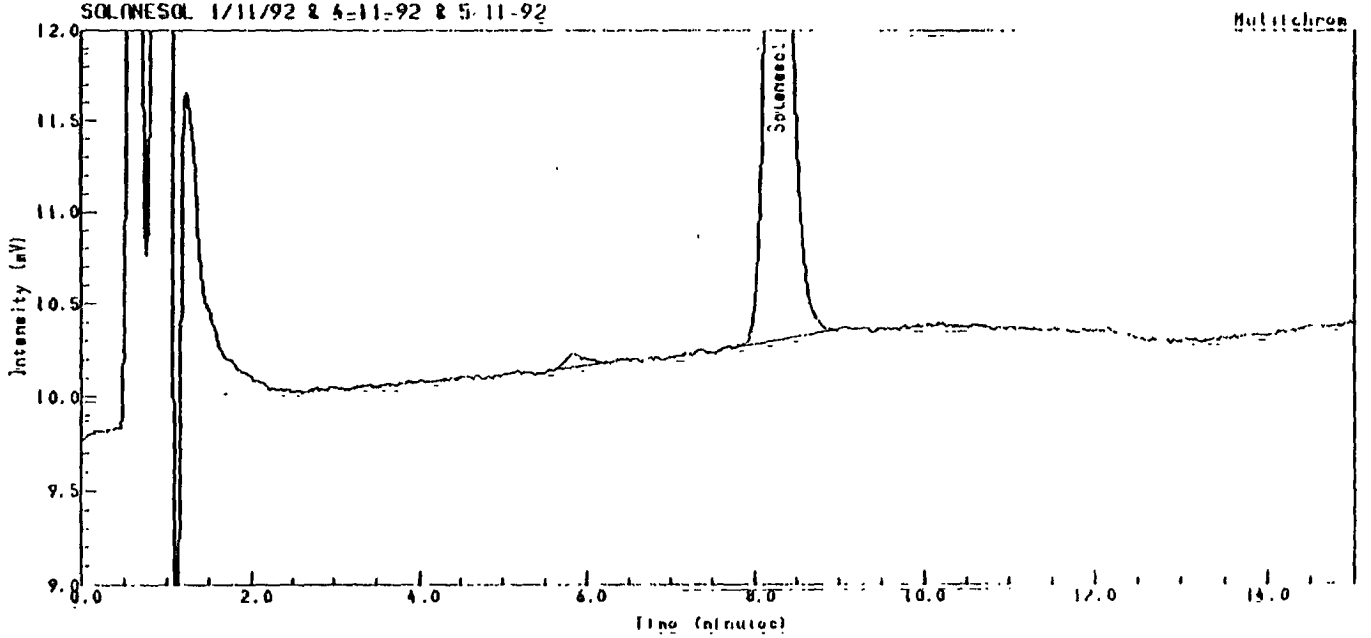
2023686521

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Typical standard calibration chromatogram
(0.25 µg/mL)

HAZLETON Bioanalytical department Multichrom 1.8

Analysis Name : EJM12_64) 4 S1-11,14,1.
Cal 0.250 Amount : 1.000
SOLANESOL 1/11/92 & 4-11-92 & 5-11-92



Instrument :
Channel Title : Channel #4
Time ID :
Acquired on 8-NOV-1992 at 22:24
Reported on 3-DEC-1992 at 13:18

Method : S1-11
Calibration : S1-11
Run Sequence : S1-11

2023686522

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

DETERMINATION OF NICOTINE

PRINCIPLE

Nicotine collected on the front filter (Millipore, Teflon) is extracted into methanol. An aliquot of this extract is basified with sodium hydroxide and the nicotine is extracted into DIPE which contains triethylamine and an internal standard.

The nicotine collected on the second, acidified, pad is basified with sodium hydroxide and the nicotine is extracted into DIPE which contains triethylamine and an internal standard.

EQUIPMENT

GC, split/splitless, NPD, integrator.

Typical GC conditions are:

Column: 10 m * 0.53 mm CPSIL5 CB (Chrompack).

Carrier gas: Helium 5 mL/min.

Initial temperature: 40°C.

Hold time: 1.0 min.

Temperature programme: 15°C/min.

Final temperature: 170°C.

Final time: 2 min.

Injection volume: 1.0 μL.

REAGENTS

Di-isopropyl ether (DIPE): 99.9% minimum (Romil Super Purity or equivalent).

DIPE solvent. Containing (1) 0.1 mL/litre triethylamine

(2) 2.0 mg/litre N-Ethylnornicotine.

Nicotine: Double distilled 99%+

3-Ethenylpyridine: Double distilled 98%+

N-Ethylnornicotine: Double distilled 99%+

CALIBRATION

Prepare a master solution containing 10 mg of nicotine and 10 mg 3-Ethenylpyridine in 1 litre of DIPE solvent (ie 10 μg/mL).

2023686523

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

NOTE: The DIPE solvent contains 0.2 mL/L of triethylamine and 4 mg/L of N-Ethylnornicotine internal standard. All dilutions from this master solution are made with the same solvent mixture.

Store this solution in a 1 litre volumetric flask.

This solution was prepared every week and stored in a refrigerator.

Prepare calibration solutions by dilution of the master solution with DIPE solvent as follows:

CONCENTRATION µg/mL	DILUTION OF MASTER
5.0	50 mL to 100 mL
2.0	20 mL to 100 mL
1.0	10 mL to 100 mL
0.50	5 mL to 100 mL
0.2	2 mL to 100 mL
0.10	1 mL to 100 mL
0.025	0.25 mL to 100 mL
0.00	0 mL to 100 mL

These calibration solutions cover a range of 0 to 25 $\mu g/m^3$ for nicotine and 3-Ethenylpyridine on the acidic filter. The calibration point of 0.025 µg/mL corresponds to 0.13 $\mu g/m^3$.

These diluted calibration solutions should be prepared fresh every week and stored in the refrigerator.

Fill an autosampler vial with each of the calibration solutions.

2023686524

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Inject each calibration solution into the GC system. Measure the area of the NPD peaks corresponding to nicotine, 3-Ethenylpyridine and the internal standard using an integrator. Prepare a calibration graph of the ratio of nicotine peak area to internal standard peak area against nicotine concentration and a corresponding graph for 3-Ethenylpyridine.

METHOD

Inject the front extract from its autosampler vial (referred to as vial A) into the GC.

Inject the acidic filter extract from its autosampler vial (referred to as vial C) into the GC.

Determine the peak areas corresponding to nicotine, 3-Ethenylpyridine and internal standard using an integrator and calculate the ratio of nicotine peak area to internal standard peak area and the equivalent ratio for 3-Ethenylpyridine.

CALCULATION

By reference to the calibration graph (or the equation of best fit), determine the nicotine and 3-Ethenylpyridine concentrations of the filter extracts in $\mu g/mL$.

Calculate the quantity of nicotine per cubic metre of air sampled as follows:

Nicotine=N*VM*1000/VA $\mu g/m^3$ for the first filter

Nicotine=N*1000/VA $\mu g/m^3$ for the second filter

Where:

N=the nicotine concentration, in $\mu g/mL$

VA=volume of air sample collected, in litres

VM=volume of methanol used to extract the millipore filter

Add the values for the first and second filters to calculate the total nicotine concentration

Calculate the 3-Ethenylpyridine quantity per cubic metre by the same method.

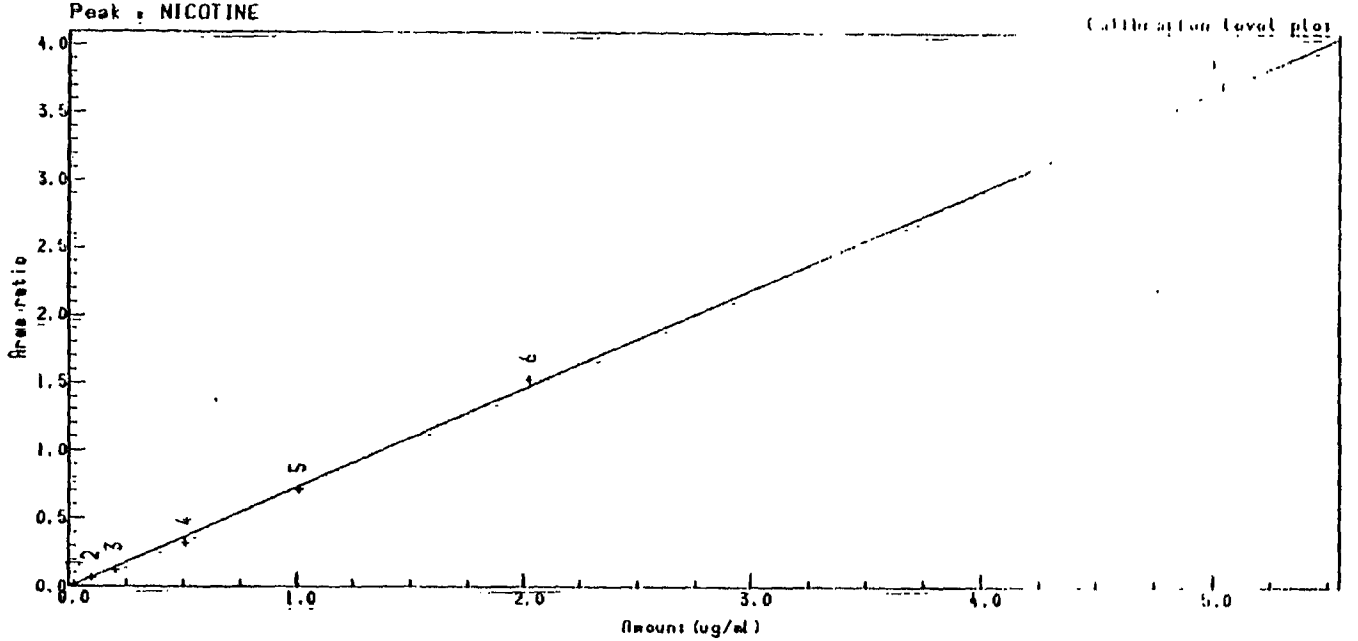
2023686525

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Typical nicotine calibration plot

HAZLETON Bioanalytical department Multichrom 1.8

Calibration Name : 34 N26-11.
N26-11
Peak : NICOTINE



Constant : -0.00514
1st degree : 0.73346

Curve fit : Linear
Correlation coefficient : 0.999[illegible]
Standard error : 0.03618

Reported on 16-DEC-1992 at 14:05

SDC 16/12/92

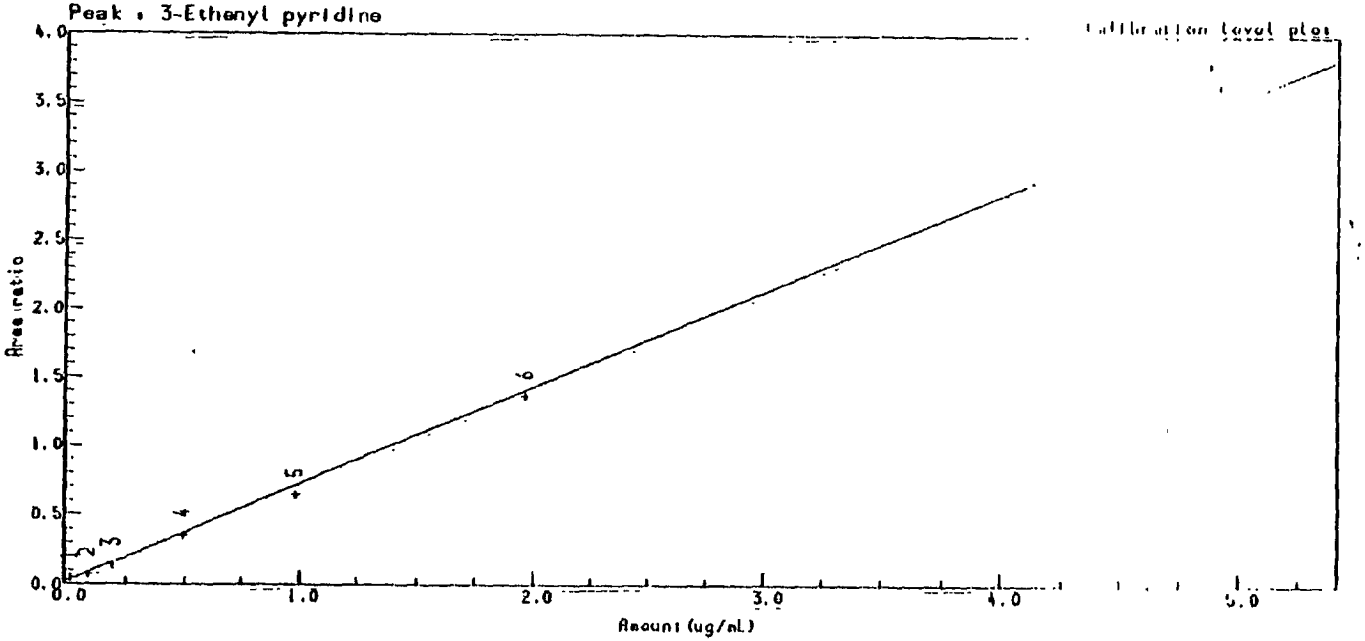
2023686526

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Typical 3-Ethenylpyridine calibration plot

HAZLETON Bioanalytical department Multichrom 1.8

Calibration Name : 34 N26-11.
N26-11
Peak : 3-Ethenyl pyridine



Constant : 0.02030
1st degree : 0.70461

Curve fit : Linear
Correlation coefficient : 0.998044
Standard error : 0.07948

Reported on 16 DEC-1992 at 14:04

16/12/92

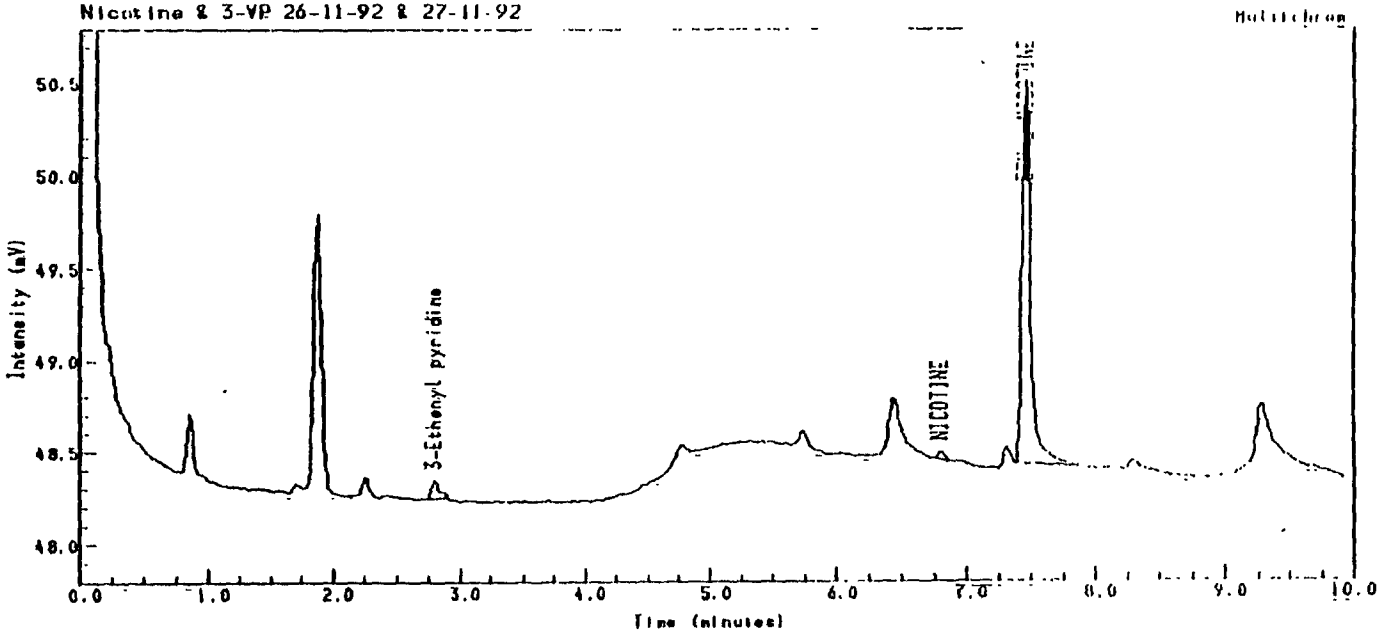
2023686527

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Typical calibration chromatogram
(0.025 µg/mL)

HAZLETON Bioanalytical department Multichrom 1.8

Analyte Name : [JM12_64] 34 N26-11.9.1.
Cal 0.025 Amount : 1.000
Nicotine & 3-VP 26-11-92 & 27-11-92



Instrument :
Channel Title : Channel #34
Time ID :
Acquired on 1-DEC-1992 at 11:43
Reported on 16-DEC-1992 at 14:25

Method : N26-11
Calibration : N26-11
Run Sequence : N26-11

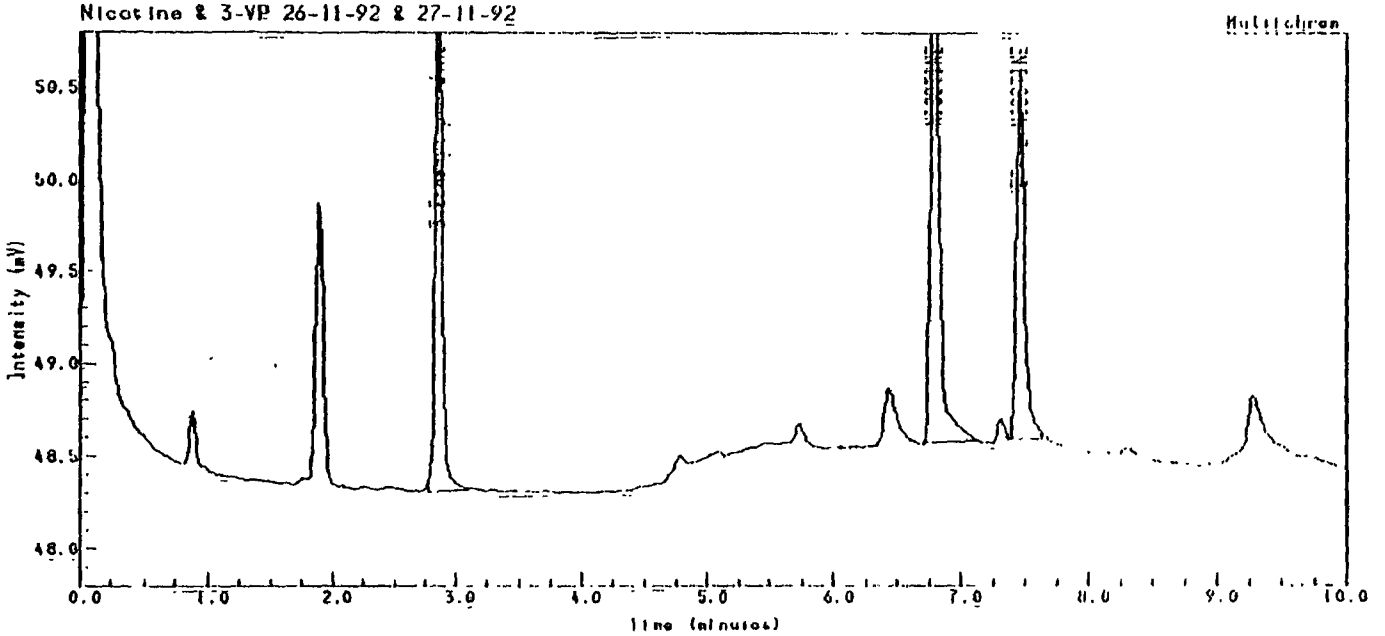
20236865 28

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Typical calibration chromatogram
(2 µg/mL)

HAZLETON Bioanalytical department Multichrom 1.0

Analysis Name : [JM12_64] 34 N26-11.4.1.
Cal 2.00 Amount : 1.000
Nicotine & 3-VP 26-11-92 & 27-11-92



Instrument :
Channel Title : Channel #34
Lims ID :
Acquired on 1-DEC-1992 at 09:42
Reported on 16-DEC-1992 at 14:24

Method : N26-11
Calibration : N26-11
Run Sequence : N26-11

(2)

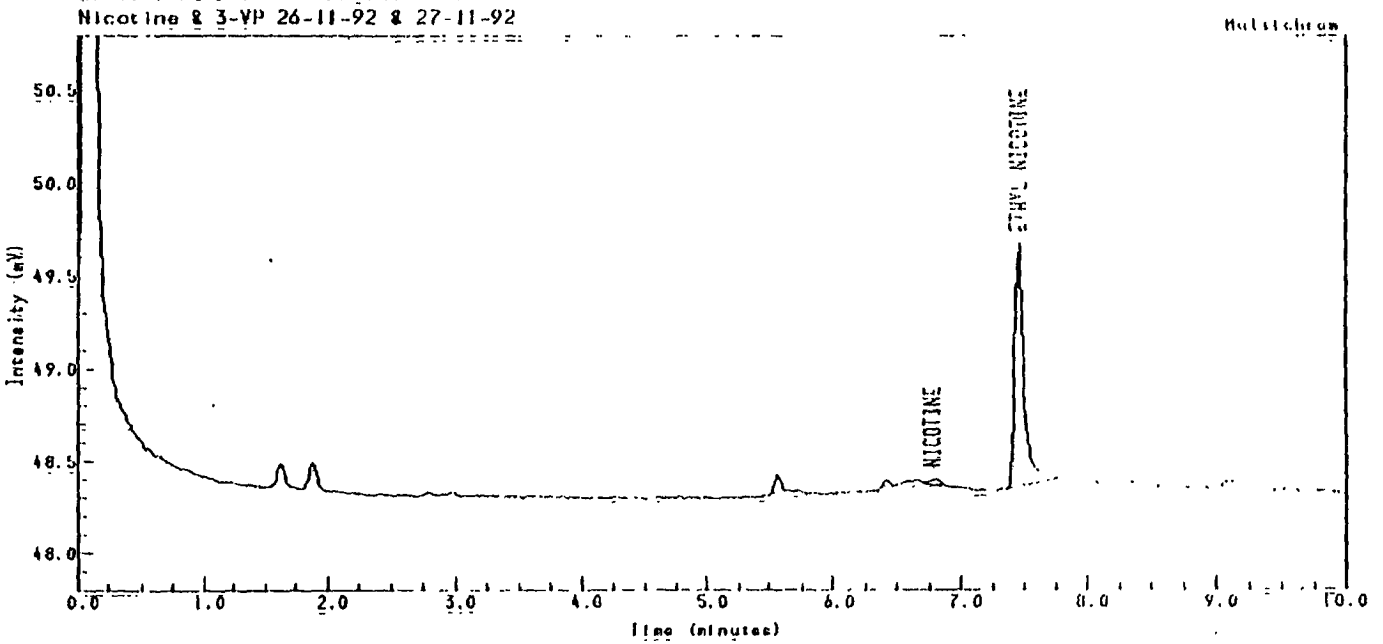
2023686529

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Typical sample chromatogram
(front Teflon filter)

HAZELTON Bioanalytical department Multichrom 1.8

Analysis Name : [JM12_64] 54 N26 11.12.1.
26-11/270-14/1 Amount : 1.000
Nicotine & 3-VP 26-11-92 & 27-11-92



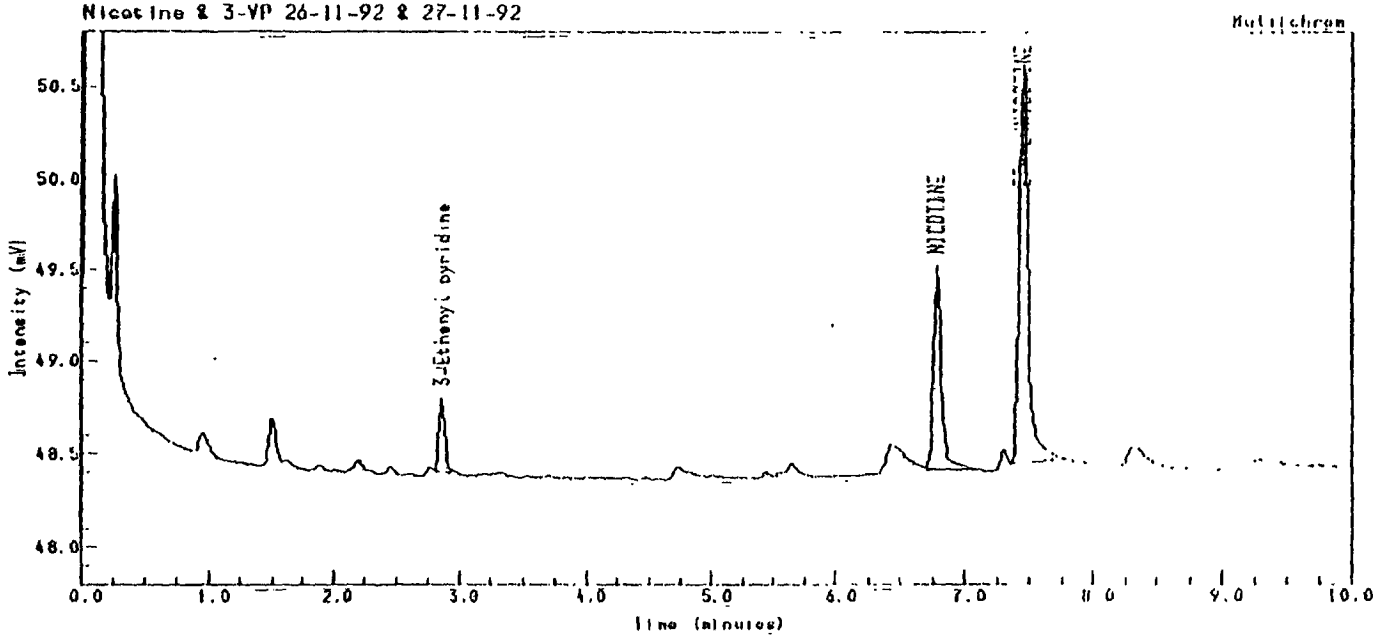
Instrument :
Channel Title : Channel #34
Lims ID :
Acquired on 1-DEC-1992 at 12:56
Reported on 16-DEC-1992 at 14:25

Method : N26-11
Calibration : N26-11
Run Sequence : N26-11

2023686530

HAZLETON Bioanalytical department Multichrom 1.8

Analyte Name : IJM12_641 34 N26-11,30,1.
27-11/275-20/2 Amount : 1.000
Nicotine & 3-VP 26-11-92 & 27-11-92



Typical sample chromatogram
(second acid filter)

Instrument :
Channel Title : Channel #34
Time ID :
Acquired on 1-DEC-1992 at 20:12
Reported on 16-DEC-1992 at 14:29

Method : N26 11
Calibration : N26-11
Run Sequence : N26-11

2023686531

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

DETERMINATION OF COTININE IN SALIVA

PRINCIPLE

The pre-centrifuged salivette containing the saliva sample is removed from the freezer and thawed. Internal standard (N-Ethylnorcotinine) is added to the saliva sample. The cotinine and internal standard are extracted into dichloromethane under basic conditions. The dichloromethane is removed by evaporation under a stream of nitrogen and the sample extract is reconstituted in a known volume of dichloromethane. The cotinine is determined by capillary GC with mass selective detection.

APPARATUS

GC, splitless injector, Mass Selective Detector, Unix Chemstation data system (GC-MSD)

GC conditions are:

Column:	12 m x 0.2 mm id, 0.33 μm film thickness HP-1 from Hewlett Packard
Carrier gas:	Helium, 20 psi head pressure
Initial temperature:	50°C
Hold time:	1 min
Temperature programme:	20°C/min
Final temperature:	250°C
Cycle time:	10.33 minutes
Injection volume:	2 μL

REAGENTS

Dichloromethane:	(BDH) GC analysis grade
Ammonium hydroxide solution:	(35%) (BDH)
Ethanol:	(Hayman Labs). Absolute grade.

2023686532

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

CALIBRATION

A master stock solution of cotinine was prepared by dissolving 4.212 mg (accurately weighed) cotinine in 10 mL ethanol. Three working standards were prepared from this stock as follows:

CONCENTRATION µg/mL	DILUTION	EQUIVALENT COTININE µg/mL
5	Master (120 µL to 10 mL)	5.05
0.5	5 µg/mL working standard (1 mL to 10 mL)	0.51
0.005	5 µg/mL working standard (100 µL to 10 mL)	0.05

From these three working standards the calibration standards were prepared by dilution as follows:

CONCENTRATION ng/mL	DILUTION	EQUIVALENT COTININE ng/mL
0.5	0.05 µg/mL (100 µL to 10 mL)	0.51
1.0	0.05 µg/mL (199 µL to 10 mL)	1.01
2.5	0.5 µg/mL (49 µL to 10 mL)	2.48
5.0	0.5 µg/mL (100 µL to 10 mL)	5.05
10.0	0.5 µg/mL (199 µL to 10 mL)	10.06
25.0	5.0 µg/mL (49 µL to 10 mL)	24.76
50	5.0 µg/mL (99 µL to 10 mL)	50.03

The calibration standards are prepared in water as all saliva tends to contain a quantity of cotinine. The calibration standards are stored in a refrigerator for no longer than two months.

These calibration solutions cover a range equivalent to 0.5 to 50 ng/mL.

QUALITY CONTROL SAMPLES

Cotinine working solutions at nominal concentrations of 2 and 0.2 µg/mL are prepared in ethanol by dilution of a stock solution. These solutions are used to prepare quality

2023686533

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

control samples in saliva obtained from non-smokers at nominal target concentrations of 1, 4, 15 and 40 ng/mL. These quality control samples were prepared at the start of the study and stored in small quantities in a freezer (-20°C) for daily use.

METHOD

0.5 mL of sample/standard/QC is placed in a small test tube (12 mm x 100 mm), 50 µL internal standard solution is added, 2 mL dichloromethane and 0.5 mL Ammonium hydroxide solution. The tube is vortexed for 10 seconds and centrifuged. The aqueous layer is removed and the dichloromethane layer transferred to a second test tube (10 mm x 75 mm). The dichloromethane layer is evaporated to dryness under nitrogen. 100 µL of dichloromethane is then added to the tube. 50 µL of this is transferred to an autosampler vial and the remaining 50 µL transferred to another autosampler vial and stored at (-20°C) for backup purposes.

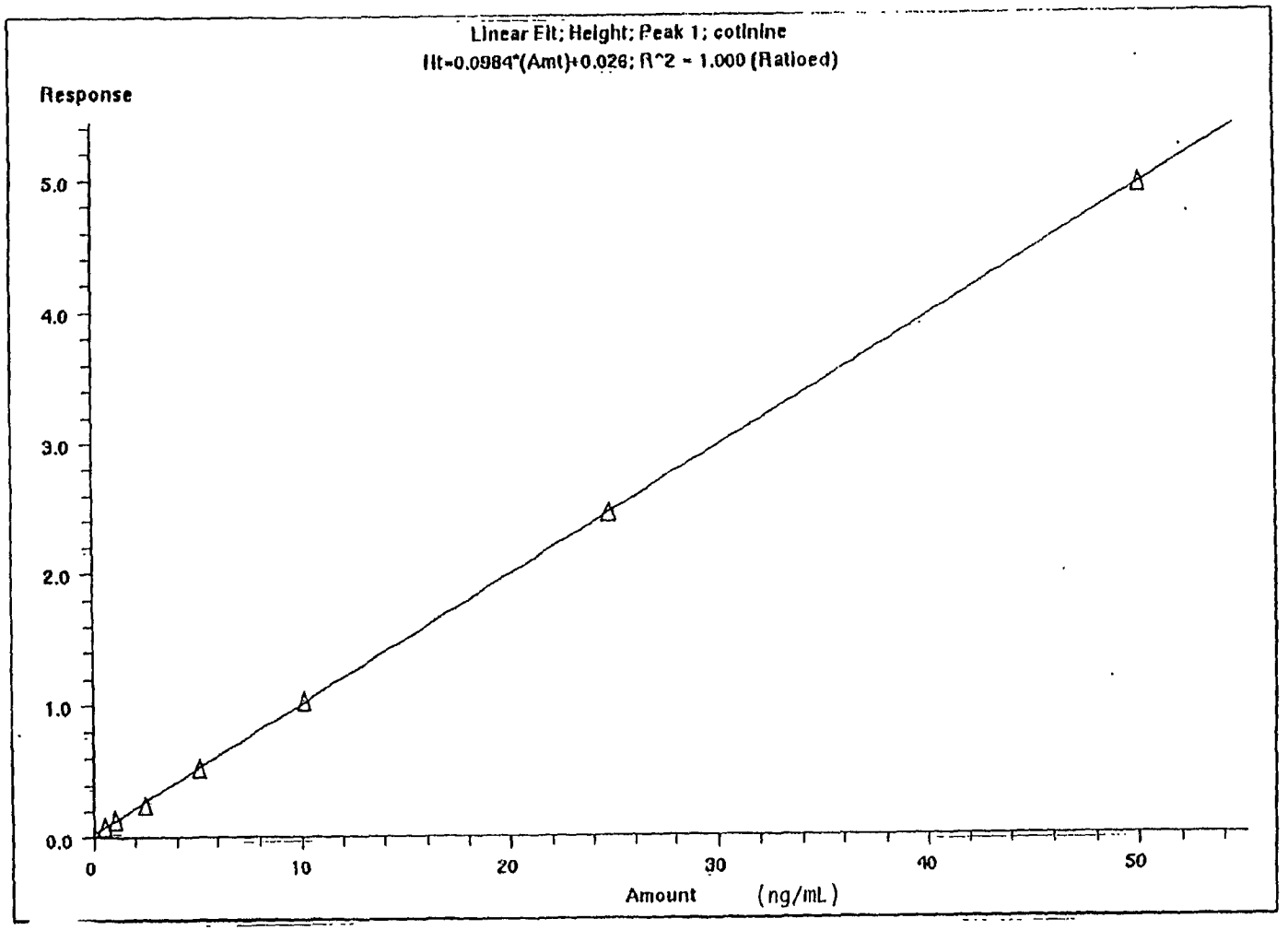
Single injections are made onto the GC-MSD. The peak height ratios of cotinine to internal standard are obtained using the data system.

CALCULATIONS

A calibration curve is constructed using the peak height ratios of the calibration standards (linear regression). The concentration of cotinine in study samples and quality control samples are obtained by interpolation of their peak height ratios.

2023686534

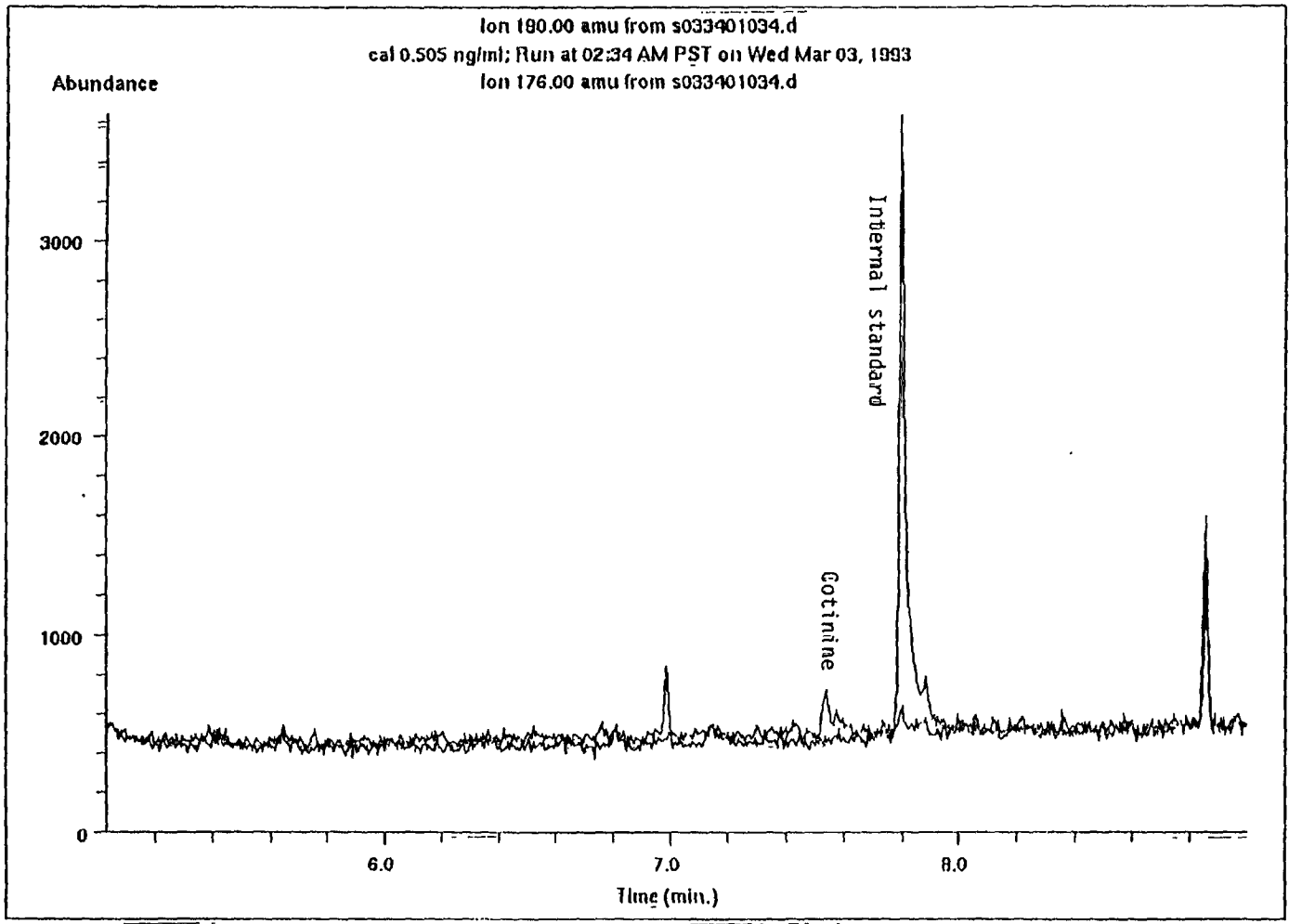
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000



Typical cotinine calibration plot

2023686535

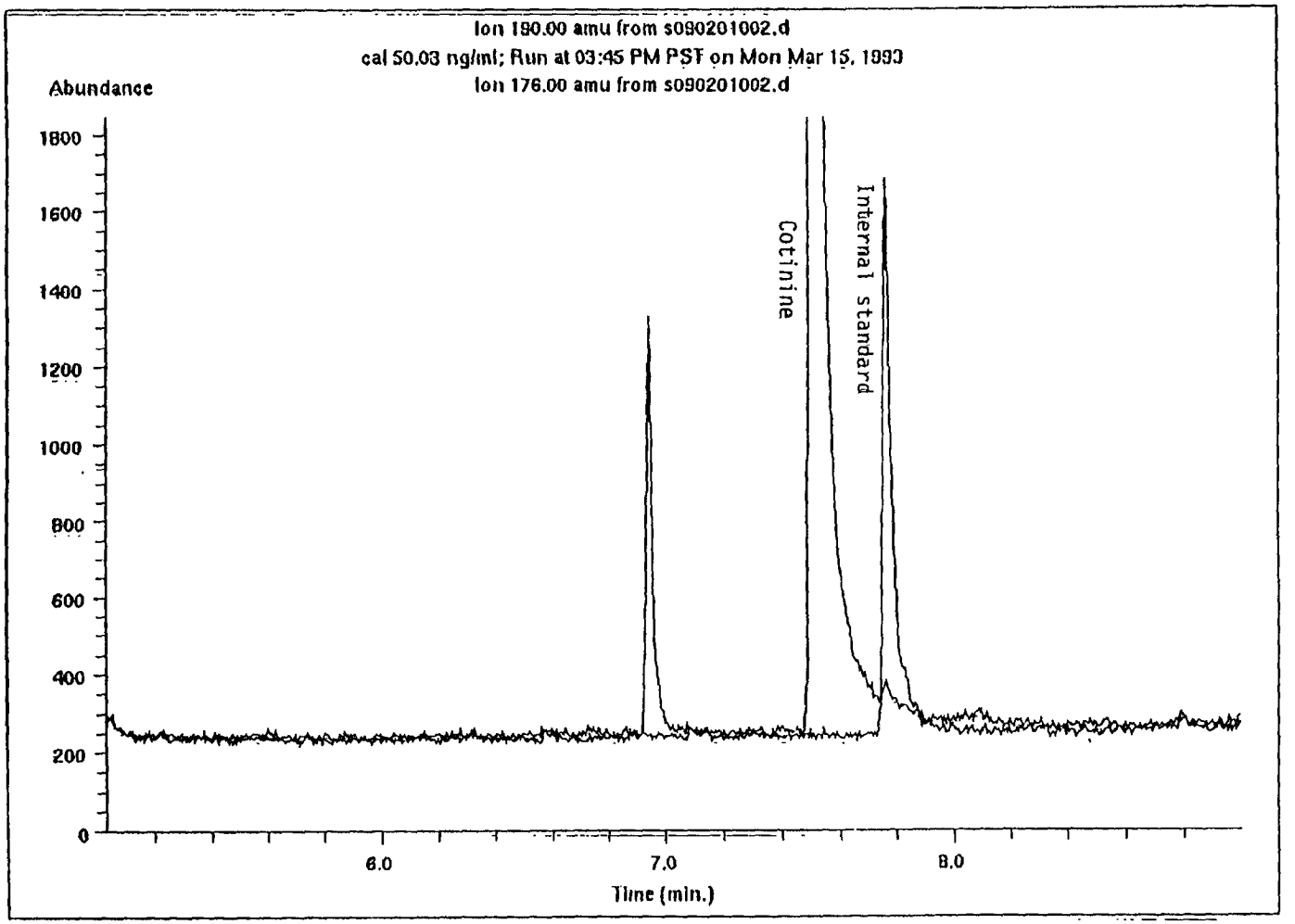
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000



Typical cotinine calibration chromatogram
(0.51 ng/mL)

2023686536

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

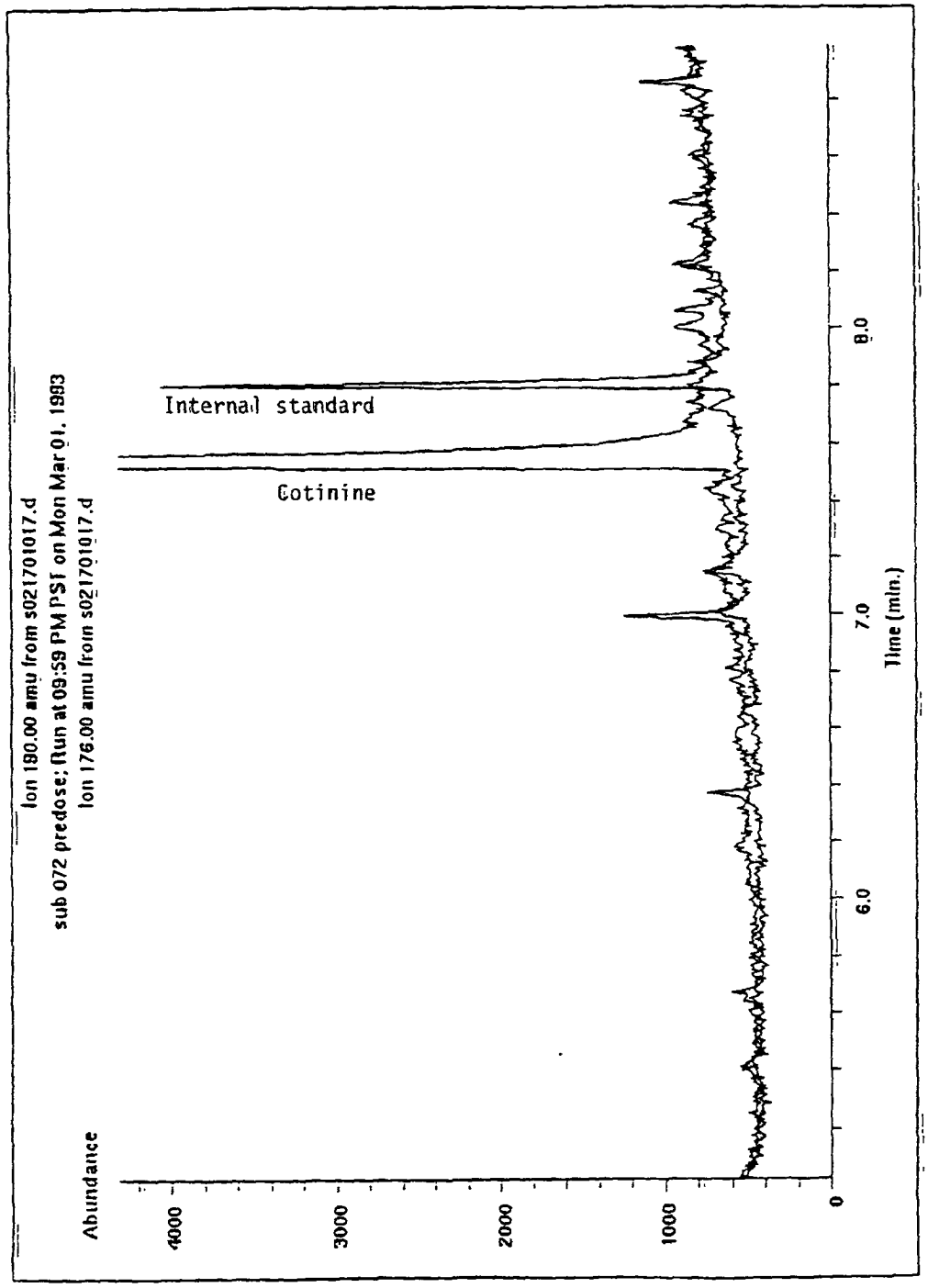


Typical cotinine calibration chromatogram
(50.03 ng/mL)

2023686537

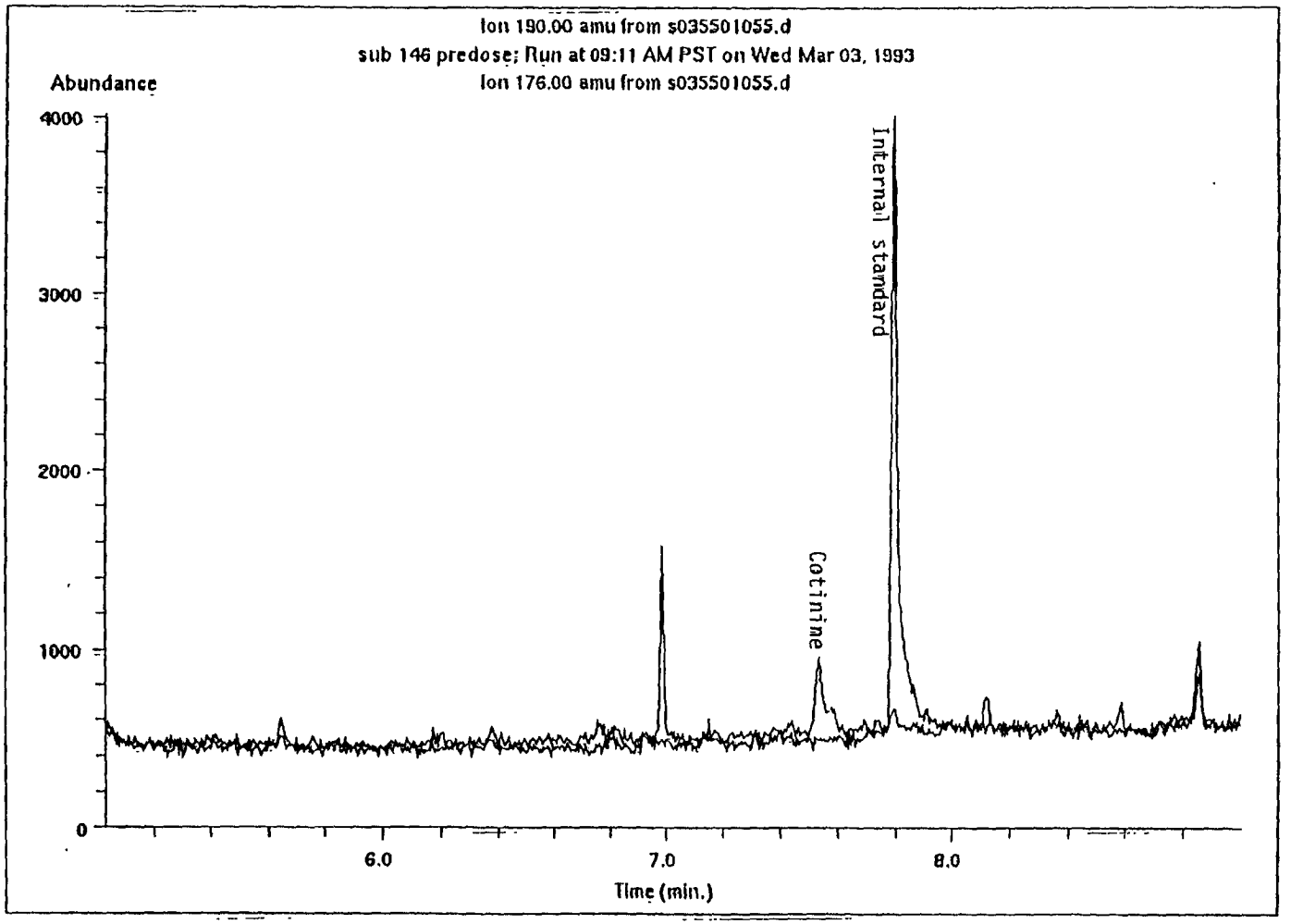
Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Typical cotinine sample
(high level subject ~ 100 ng/mL)



2023686538

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000



Typical cotinine sample chromatogram
(low level subject - 1 ng/mL)

2023686539

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

APPENDIX 5

MISCELLANEOUS INFORMATION

2023686540

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

APPENDIX 5.1

ETHICAL APPROVAL FOR THE CONDUCT OF THE STUDY

2023686541

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

PHILLIPS

GHBA/Hazleton Clinics
Leeds

INDEPENDENT REVIEW BOARD

CONSTITUTION

1. Name and Purpose

1.1 The Board shall be called the "Independent Review Board".

1.2 The responsibility of the IRB shall be:

- to protect the safety, rights and dignity of human subjects involved in clinical research studies
- to ensure the science warrants exposure of subjects to risk
- to ensure that applicable laws, regulations and standard operating procedures are followed.

2. Membership

2.1 The Board shall consist of twenty members.

2.2 The Board must include at least one woman and one man.

2.3 At least one member must be a registered medical practitioner.

2.4 At least one member must represent a non-scientific field.

2.5 A quorum consists of five members and must include a registered medical practitioner, a non-medical scientist and a non-scientist, both sexes should be represented.

2.6 Members shall serve for one year terms from 1 August. Consecutive terms of service are encouraged to provide continuity to the Board's activities.

2.7 It is the responsibility of the Managing Director of GHBA/Hazleton Clinic Leeds to nominate members of the IRB. The Chairman is appointed by the Managing Director of GHBA/Hazleton Clinic Leeds for a one year term which may be renewed at the MD's discretion.

3. Authority

3.1 The IRB has the sole power to approve, modify or disapprove all study protocols and informed consents for studies involving human subjects.

2023686542

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

3.2 Requirements for modification or disapproval of either a protocol or an informed consent may not be over-ruled by any number of GHBA/Hazleton's staff.

4. Meetings

Meetings are scheduled for the first and third Tuesday of every month at 6.30 p.m. Meetings are held at GHBA/Hazleton Clinic Leeds. If a meeting is not required, the Medical Director will inform the Chairman so Board members can be notified of the cancellation.

5. Voting

5.1 Voting will be oral upon a call of roll of the members present.

5.2 The decision of the IRB to approve or disapprove will be that expressed by a majority of the members present with all votes carrying equal weight. In the case of approval, at least one of the affirmative votes must be cast by a physician.

6. Reporting Results of Review

Results of an IRB review are submitted to the Principal Investigator on a pro forma, signed by the Chairman, or his alternate. This form will also include any requirements for amendment or modification to the protocol or informed consent.

7. Records

The IRB will be required to maintain:

7.1 Copies of all research proposal documentation submitted for review, together with completion notices detailing any adverse events.

7.2 Minutes of meetings to contain the names of members and others in attendance, decisions of the Board and the basis for disapproval of any proposal. Individual votes will be recorded.

7.3 A file containing name and qualifications of each member of the Board and their representative capacity.

7.4 A set of Standard Operating Procedures (both current and historical) which shall be circulated to each member and alternate at least once every twelve months.

8. Finance

8.1 Members shall receive travelling expenses for attendance at meetings.

8.2 GHBA/Hazleton will pay the sum of £15 per protocol reviewed either to each member or to a charity of their choice.

This Constitution is a resume of the Standard Operating Procedures by which the function of the IRB is regulated.

2023686543

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

APPENDIX 6
TABLES

2023665H

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

APPENDIX 6.1

ANALYTICAL RESULTS FOR ALL SUBJECTS

2023686545

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 1

ANALYTICAL RESULTS FOR ALL SUBJECTS

Subject number	PAS ($\mu g/m^3$)	UVPM ($\mu g/m^3$)	FPM ($\mu g/m^3$)	SPM ($\mu g/m^3$)	Nicotine ($\mu g/m^3$)	3-eth ($\mu g/m^3$)	Pre Cot (ng/mL)	Post Cot (ng/mL)
1	142	15	5	4	0.20	ND	1.1	1.0
2	164	11	4	ND	ND	ND	ND	ND
3	123	20	8	ND	0.83	ND	1.0	1.0
4	321	23	11	6	0.32	ND	1.3	0.9
5	103	12	6	ND	ND	ND	ND	0.6
7	170	41	23	16	1.5	0.41	5.3	5.8
8	91	22	13	12	2.5	ND	1.4	1.5
9	133	39	19	17	2.3	0.55	1.3	1.6
10	105	65	19	ND	0.86	0.15	0.7	0.6
12	213	17	9	11	0.33	ND	1.1	0.6
13	219	15	6	ND	ND	ND	0.7	0.5
14	103	9	5	ND	0.28	ND	0.8	0.6
15	377	21	8	ND	ND	ND	0.7	ND
16	134	48	33	59	7.2	0.99	0.6	5.7
17	52	15	6	ND	ND	ND	0.7	ND
18	63	287	9	ND	ND	ND	1.1	0.8
19	378	31	13	ND	0.15	ND	2.0	1.0

ND = Not detected NA = Not analysed

HUK Study no. 12/64

2023686546

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 1 (continued)

ANALYTICAL RESULTS FOR ALL SUBJECTS

Subject number	PAS ($\mu g/m^3$)	UVPM ($\mu g/m^3$)	FPM ($\mu g/m^3$)	SPM ($\mu g/m^3$)	Nicotine ($\mu g/m^3$)	3-eth ($\mu g/m^3$)	Pre Cot (ng/mL)	Post Cot (ng/mL)
20	228	20	7	6	0.13	ND	0.8	0.6
22	404	36	21	32	2.9	1.0	2.0	2.5
23	294	16	8	ND	NA	NA	1.2	0.8
24	295	67	28	38	3.6	1.1	5.1	7.9
25	139	35	12	11	1.3	0.36	1.4	NA
26	116	9	6	ND	ND	ND	0.7	0.6
27	134	74	22	ND	ND	ND	0.7	ND
28	74	66	6	ND	ND	ND	2.2	1.7
29	252	23	13	5	0.53	0.74	0.9	0.8
30	35	8	9	ND	0.23	0.33	1.1	0.8
31	106	64	38	44	3.9	1.1	0.7	0.8
32	103	12	7	ND	ND	ND	ND	0.6
33	211	26	23	29	3.0	0.84	1.3	1.5
35	29	ND	6	ND	0.29	ND	0.5	0.6
36	244	ND	7	ND	0.28	ND	0.6	0.6
37	273	46	18	11	1.0	ND	7.4	NA
39	249	43	26	20	3.4	0.67	1.5	1.7

ND = Not detected NA = Not analysed

2023686547

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 1 (continued)

ANALYTICAL RESULTS FOR ALL SUBJECTS

Subject number	PAS ($\mu g/m^3$)	UVPM ($\mu g/m^3$)	FPM ($\mu g/m^3$)	SPM ($\mu g/m^3$)	Nicotine ($\mu g/m^3$)	3-eth ($\mu g/m^3$)	Pre Cot (ng/mL)	Post Cot (ng/mL)
40	106	15	7	ND	3.1	ND	0.7	ND
41	219	25	16	14	2.6	0.55	8.2	7.5
42	254	11	6	ND	0.23	ND	0.7	0.5
43	121	61	9	ND	NA	NA	0.9	1.0
45	178	28	17	9	4.4	0.33	7.9	3.6
46	161	14	10	8	1.4	0.19	3.1	1.2
47	129	116	10	ND	0.41	0.16	1.0	ND
48	112	48	7	ND	NA	NA	0.5	ND
49	71	15	9	6	1.5	0.46	0.7	ND
51	93	10	ND	ND	ND	ND	0.6	ND
52	314	51	33	38	4.1	1.1	0.7	ND
53	78	23	94	12	ND	ND	1.8	5.8
54	197	41	7	ND	ND	ND	0.9	ND
55	140	12	ND	ND	ND	ND	ND	ND
57	173	56	18	23	1.3	ND	3.4	NA
58	172	12	ND	ND	ND	ND	0.7	ND
59	104	41	10	ND	0.89	ND	1.3	ND

ND = Not detected NA = Not analysed

MUK Study no. 12/64

2023686548

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 1 (continued)

ANALYTICAL RESULTS FOR ALL SUBJECTS

Subject number	PAS ($\mu g/m^3$)	UVPM ($\mu g/m^3$)	FPM ($\mu g/m^3$)	SPM ($\mu g/m^3$)	Nicotine ($\mu g/m^3$)	3-eth ($\mu g/m^3$)	Pre Cot (ng/mL)	Post Cot (ng/mL)
60	70	14	8	ND	ND	ND	1.0	ND
61	163	21	7	ND	ND	ND	1.0	ND
62	55	9	ND	ND	ND	ND	ND	ND
63	90	9	ND	7	ND	ND	1.9	ND
64	190	299	10	ND	ND	ND	ND	ND
66	110	18	6	ND	ND	ND	1.0	ND
67	315	70	41	69	8.8	1.4	3.2	3.3
68	216	27	6	ND	ND	ND	1.8	ND
70	182	19	21	10	0.74	ND	1.4	0.6
71	71	9	7	ND	ND	ND	ND	ND
73	281	8	ND	ND	0.29	ND	ND	ND
74	995	72	146	ND	0.18	ND	ND	ND
77	195	16	ND	ND	0.47	ND	ND	ND
78	151	169	28	88	5.2	1.9	8.4	7.0
79	85	178	ND	ND	0.41	ND	ND	ND
80	94	17	ND	ND	0.19	0.32	ND	ND
82	167	39	24	24	4.8	0.89	ND	ND

ND = Not detected NA = Not analysed

2023686549

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE I (continued)

ANALYTICAL RESULTS FOR ALL SUBJECTS

Subject number	PAS ($\mu g/m^3$)	UVPM ($\mu g/m^3$)	FPM ($\mu g/m^3$)	SPM ($\mu g/m^3$)	Nicotine ($\mu g/m^3$)	3-eth ($\mu g/m^3$)	Pre Cot (ng/mL)	Post Cot (ng/mL)
83	63	18	5	ND	0.50	ND	1.2	ND
84	138	46	18	10	1.9	0.29	ND	ND
85	372	23	9	ND	ND	ND	ND	ND
86	104	13	ND	ND	0.22	0.41	ND	ND
87	112	21	10	11	0.47	0.46	ND	0.6
88	1219	29	18	19	3.7	1.1	4.1	4.2
89	179	14	6	ND	ND	ND	1.8	6.7
90	139	38	24	25	0.46	0.92	1.3	0.7
91	105	127	6	ND	ND	ND	0.7	ND
92	20	ND	ND	ND	ND	ND	ND	ND
93	97	11	13	ND	0.21	ND	2.4	2.5
94	78	12	ND	ND	0.17	ND	ND	ND
95	116	21	11	12	1.6	2.7	5.5	2.4
96	286	59	40	50	9.4	1.5	ND	0.8
97	549	10	7	ND	1.2	ND	0.6	ND
100	131	16	11	5	0.40	0.47	0.6	1.6
101	48	15	9	ND	2.3	0.79	0.9	1.4

ND = Not detected NA = Not analysed

2023686550

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 1 (continued)

ANALYTICAL RESULTS FOR ALL SUBJECTS

Subject number	PAS ($\mu g/m^3$)	UVPM ($\mu g/m^3$)	FPM ($\mu g/m^3$)	SPM ($\mu g/m^3$)	Nicotine ($\mu g/m^3$)	3-eth ($\mu g/m^3$)	Pre Cot (ng/mL)	Post Cot (ng/mL)
102	74	13	10	8	ND	ND	2.1	0.6
103	294	29	13	7	0.60	ND	ND	ND
104	111	10	ND	ND	ND	ND	ND	ND
105	272	51	33	59	5.5	1.4	1.4	1.8
106	89	42	33	44	5.4	1.5	1.2	1.5
107	176	18	12	ND	0.21	ND	ND	ND
108	322	63	47	87	11	1.3	0.8	0.7
109	181	37	20	22	1.2	0.23	0.7	ND
112	539	20	14	ND	ND	ND	ND	ND
113	88	13	6	8	0.61	0.18	ND	ND
114	163	41	21	18	2.7	0.62	ND	ND
115	93	22	8	16	0.31	0.13	ND	ND
118	143	49	30	38	13	2.3	2.6	4.3
119	108	38	17	ND	3.5	ND	0.6	ND
120	69	20	12	ND	0.41	ND	3.8	1.5
121	368	91	68	87	18	3.0	4.2	8.1
122	87	32	9	ND	1.4	ND	ND	ND

ND = Not detected NA = Not analysed

HUK Study no 12/64

2023686551

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE I (continued)

ANALYTICAL RESULTS FOR ALL SUBJECTS

Subject number	PAS ($\mu g/m^3$)	UVPM ($\mu g/m^3$)	FPM ($\mu g/m^3$)	SPM ($\mu g/m^3$)	Nicotine ($\mu g/m^3$)	3-eth ($\mu g/m^3$)	Pre Cot (ng/mL)	Post Cot (ng/mL)
123	123	20	13	ND	0.63	ND	ND	ND
135	276	46	23	5	1.7	ND	2.3	1.6
137	99	18	7	ND	0.79	ND	NA	ND
138	208	18	ND	ND	0.72	ND	ND	ND
139	141	13	ND	ND	ND	ND	ND	ND
145	395	14	ND	ND	3.3	ND	0.7	0.7
146	185	19	ND	10	2.0	0.23	1.0	ND
147	131	15	ND	ND	0.61	ND	ND	ND
148	173	26	9	17	1.3	0.52	1.1	1.4
150	119	12	ND	ND	0.30	ND	ND	NA
151	219	25	20	ND	0.14	0.14	ND	1.0
152	86	20	6	ND	0.57	ND	2.0	1.0
153	129	16	ND	ND	ND	ND	1.2	ND
154	64	15	ND	ND	ND	ND	0.9	ND
155	35	16	6	ND	ND	ND	ND	ND
156	65	18	ND	ND	0.15	ND	1.1	ND
157	151	48	43	ND	ND	ND	0.7	ND

ND = Not detected NA = Not analysed

HUK Study no 12/64

2023686552

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 1 (continued)

ANALYTICAL RESULTS FOR ALL SUBJECTS

Subject number	PAS ($\mu g/m^3$)	UVPM ($\mu g/m^3$)	FPM ($\mu g/m^3$)	SPM ($\mu g/m^3$)	Nicotine ($\mu g/m^3$)	3-eth ($\mu g/m^3$)	Pre Cot (ng/mL)	Post Cot (ng/mL)
159	92	26	17	ND	0.14	0.23	1.3	ND
166	54	18	ND	ND	0.32	ND	0.9	4.5
168	378	46	18	27	3.6	ND	13.0	2.3
169	107	36	11	17	NA	NA	1.5	3.2
170	222	31	15	ND	NA	NA	1.4	2.3
171	137	32	11	ND	NA	NA	1.1	0.6
172	460	35	12	ND	1.7	ND	2.1	1.3
173	205	32	14	17	0.76	ND	1.0	2.1
174	113	18	6	ND	ND	ND	ND	0.9
175	99	20	8	ND	1.1	ND	1.2	1.8
176	83	22	9	ND	ND	ND	ND	0.7
177	155	43	20	16	3.4	0.9	2.6	12.4
178	129	12	7	ND	ND	ND	1.1	1.4
179	184	61	22	5	0.48	ND	1.5	1.0
180	229	14	8	ND	0.21	ND	0.8	ND
181	199	60	35	55	0.44	0.17	0.9	3.4
182	151	67	10	70	2.2	ND	5.2	5.3

ND = Not detected NA = Not analysed

2023686553

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 1 (continued)

ANALYTICAL RESULTS FOR ALL SUBJECTS

Subject number	PAS ($\mu g/m^3$)	UVPM ($\mu g/m^3$)	FPM ($\mu g/m^3$)	SPM ($\mu g/m^3$)	Nicotine ($\mu g/m^3$)	3-eth ($\mu g/m^3$)	Pre Cot (ng/mL)	Post Cot (ng/mL)
183	481	19	ND	ND	ND	ND	1.2	1.1
184	152	41	20	26	1.5	0.57	ND	6.8
185	75	13	11	ND	ND	ND	1.0	4.7
186	156	10	ND	ND	ND	ND	ND	2.1
187	94	16	11	ND	0.78	0.35	1.2	7.8
188	115	9	ND	ND	ND	ND	0.9	ND
189	76	7	6	ND	ND	ND	0.9	3.6
190	524	43	11	13	2.9	0.82	2.8	5.0
191	300	38	14	22	3.8	0.52	1.5	1.8
192	106	29	22	ND	2.1	0.20	1.0	1.1
193	207	31	19	ND	0.30	ND	ND	NA
194	104	12	6	ND	0.26	0.14	2.7	3.7
195	153	21	ND	ND	0.51	0.14	1.4	0.7
196	296	24	6	ND	0.93	ND	ND	1.7
197	147	24	9	9	1.5	0.46	ND	1.0
198	78	21	ND	ND	ND	ND	ND	ND
199	156	32	15	13	0.87	0.22	0.5	ND

ND = Not detected NA = Not analysed

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2023686554

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 1 (continued)

ANALYTICAL RESULTS FOR ALL SUBJECTS

Subject number	PAS ($\mu g/m^3$)	UVPM ($\mu g/m^3$)	FPM ($\mu g/m^3$)	SPM ($\mu g/m^3$)	Nicotine ($\mu g/m^3$)	3-eth ($\mu g/m^3$)	Pre Cot (ng/mL)	Post Cot (ng/mL)
200	268	21	7	ND	0.25	ND	ND	1.2
201	123	17	ND	ND	0.31	ND	ND	ND
202	203	37	33	22	3.4	0.50	1.2	3.1
203	182	22	19	ND	0.35	ND	ND	ND
204	57	19	17	ND	ND	ND	ND	ND
205	187	66	50	64	9.2	2.5	0.8	ND
206	153	32	38	ND	1.0	0.18	ND	ND
207	222	54	38	50	0.69	0.35	0.8	12.1
208	65	26	11	ND	1.6	ND	2.1	ND
209	847	30	13	ND	0.75	ND	ND	ND
210	129	62	35	42	3.6	0.78	ND	ND
214	149	10	8	9	1.4	ND	ND	ND
215	138	44	38	51	11	2.4	2.0	2.6
216	159	24	17	18	5.6	0.78	ND	0.7
219	256	17	22	8	2.3	0.19	1.1	ND
220	95	35	ND	ND	1.0	ND	ND	ND
221	55	14	6	ND	1.9	ND	ND	ND

ND = Not detected NA = Not analysed

2023686555

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 1 (continued)

ANALYTICAL RESULTS FOR ALL SUBJECTS

Subject number	PAS ($\mu g/m^3$)	UVPM ($\mu g/m^3$)	FPM ($\mu g/m^3$)	SPM ($\mu g/m^3$)	Nicotine ($\mu g/m^3$)	3-eth ($\mu g/m^3$)	Pre Cot (ng/mL)	Post Cot (ng/mL)
222	81	11	ND	ND	ND	ND	0.7	0.8
223	112	12	9	5	1.8	0.54	2.4	0.8
224	180	13	10	ND	ND	ND	ND	ND
225	70	11	ND	ND	ND	ND	ND	ND
226	124	19	8	5	2.0	0.37	1.3	7.1
227	115	21	11	ND	0.98	0.41	14.0	5.9
228	282	17	6	ND	1.0	0.28	ND	ND
229	45	12	ND	ND	ND	ND	ND	ND
230	191	109	8	ND	1.3	0.15	ND	ND
232	60	12	ND	ND	0.26	ND	ND	ND
233	338	24	8	8	1.0	0.26	0.7	ND
234	71	30	14	23	1.4	0.31	ND	NA
235	205	45	9	5	1.3	ND	ND	ND
236	125	21	16	ND	0.62	ND	ND	ND
237	149	29	26	ND	0.44	ND	ND	ND
238	178	47	55	6	1.4	0.19	ND	ND
239	257	27	13	7	0.79	0.32	ND	ND

ND = Not detected NA = Not analysed

2023686556

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 1 (continued)

ANALYTICAL RESULTS FOR ALL SUBJECTS

Subject number	PAS ($\mu g/m^3$)	UVPM ($\mu g/m^3$)	FPM ($\mu g/m^3$)	SPM ($\mu g/m^3$)	Nicotine ($\mu g/m^3$)	3-eth ($\mu g/m^3$)	Pre Cot (ng/mL)	Post Cot (ng/mL)
240	313	46	19	ND	ND	ND	ND	ND
241	59	23	22	ND	3.1	1.3	3.5	4.2
242	149	25	18	ND	ND	ND	ND	ND
243	222	45	65	10	4.9	0.74	2.5	6.9
244	172	16	12	ND	0.52	ND	ND	3.6
245	111	35	34	ND	ND	ND	ND	3.3
246	45	8	ND	ND	ND	ND	ND	1.6
247	119	14	ND	ND	ND	ND	ND	1.7
248	127	17	ND	ND	ND	ND	ND	ND
249	154	15	7	ND	0.24	ND	ND	ND
251	30	8	7	ND	ND	ND	ND	ND
255	65	14	ND	5	0.30	0.20	13.0	6.6
256	96	ND	ND	ND	ND	ND	ND	ND
257	199	17	15	11	2.6	0.68	ND	ND
260	92	ND	7	ND	0.20	ND	ND	NA
262	108	ND	13	ND	0.29	0.39	5.8	1.2
263	275	71	45	78	19	2.2	2.6	2.4

ND = Not detected NA = Not analysed

2023686557

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 1 (continued)

ANALYTICAL RESULTS FOR ALL SUBJECTS

Subject number	PAS ($\mu g/m^3$)	UVPM ($\mu g/m^3$)	FPM ($\mu g/m^3$)	SPM ($\mu g/m^3$)	Nicotine ($\mu g/m^3$)	3-eth ($\mu g/m^3$)	Pre Cot (ng/mL)	Post Cot (ng/mL)
264	94	15	10	7	2.8	0.60	ND	ND
265	84	ND	ND	ND	0.18	ND	ND	ND
266	185	ND	ND	ND	0.31	ND	ND	ND
267	451	ND	ND	ND	ND	ND	ND	ND
268	140	11	11	ND	0.73	ND	ND	ND
269	88	10	7	ND	ND	ND	ND	ND
271	137	ND	ND	ND	ND	ND	ND	ND
272	114	ND	ND	ND	ND	ND	2.3	1.6
273	49	ND	ND	ND	0.35	ND	ND	ND
274	100	47	7	ND	0.38	ND	ND	ND
275	221	42	24	38	4.1	0.82	3.1	2.5
276	359	11	6	ND	0.18	ND	0.7	ND
277	242	75	57	87	6.9	1.3	0.7	1.3
279	362	81	74	98	15	1.9	1.5	1.7
280	154	73	30	11	4.3	0.54	2.4	ND
281	111	17	45	ND	ND	ND	ND	ND
282	208	35	46	41	7.2	1.1	3.4	2.8

ND = Not detected NA = Not analysed

2023686558

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 1 (continued)

ANALYTICAL RESULTS FOR ALL SUBJECTS

Subject number	PAS ($\mu g/m^3$)	UVPM ($\mu g/m^3$)	FPM ($\mu g/m^3$)	SPM ($\mu g/m^3$)	Nicotine ($\mu g/m^3$)	3-eth ($\mu g/m^3$)	Pre Cot (ng/mL)	Post Cot (ng/mL)
283	227	60	72	42	4.8	0.56	ND	0.6
284	135	20	41	9	0.23	0.27	ND	ND
285	221	10	7	ND	ND	ND	ND	ND
286	242	22	14	ND	ND	ND	ND	ND
287	121	9	9	7	0.92	0.46	0.7	ND
288	150	ND	11	ND	ND	ND	3.5	2.0
289	360	133	110	159	26	4.2	4.4	6.3
290	157	9	9	7	2.3	0.20	1.4	0.7
292	50	8	6	ND	3.7	0.73	0.8	ND
293	122	8	ND	ND	0.29	0.22	0.6	ND
295	164	82	43	58	12	2.2	6.8	7.7
296	138	ND	ND	ND	1.5	0.19	0.7	ND
297	259	21	ND	ND	0.16	ND	0.9	ND
298	122	12	ND	ND	ND	ND	ND	ND
299	71	10	ND	ND	ND	ND	ND	ND
302	169	35	12	7	2.5	1.1	4.6	2.5
303	380	ND	ND	ND	ND	ND	ND	ND

ND = Not detected NA = Not analysed

2023686559

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 1 (continued)

ANALYTICAL RESULTS FOR ALL SUBJECTS

Subject number	PAS ($\mu g/m^3$)	UVPM ($\mu g/m^3$)	FPM ($\mu g/m^3$)	SPM ($\mu g/m^3$)	Nicotine ($\mu g/m^3$)	3-eth ($\mu g/m^3$)	Pre Cot (ng/mL)	Post Cot (ng/mL)
304	128	14	ND	ND	ND	ND	ND	ND
305	148	15	ND	ND	ND	ND	0.6	ND
311	295	47	34	42	9.6	2.0	2.3	2.6
312	35	15	11	ND	0.16	ND	ND	ND
313	179	19	10	7	1.9	1.0	4.4	2.8
314	75	12	6	ND	1.1	1.2	1.4	ND
315	420	11	9	ND	1.2	0.22	1.6	0.7
316	79	16	9	7	1.4	0.92	5.3	4.6
317	129	44	36	68	3.8	2.7	2.5	1.6
318	420	119	84	153	8.9	2.2	2.3	1.8
319	497	23	20	5	1.8	0.31	1.1	ND
320	286	19	18	10	1.9	1.3	5.9	3.6
321	163	75	62	97	2.2	1.1	2.6	2.4
322	56	19	10	7	1.9	0.47	2.0	0.7
323	277	30	19	13	2.2	1.4	ND	ND
324	81	76	11	ND	ND	ND	3.0	1.5
327	223	12	9	ND	1.2	1.0	3.2	1.0

ND = Not detected NA = Not analysed

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2023686560

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

APPENDIX 6.2

MONITORING DATE, PERSONAL DETAILS, EXPOSURE TIME AND RATINGS FOR ALL SUBJECTS

2023686561

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 2

MONITORING DATE, PERSONAL DETAILS, EXPOSURE TIME AND RATING FOR ALL SUBJECTS

Sub No	Monitoring Date	Sex	Age (years)	Partner "status"	Overall rating of Exposure	Overall Estimate of Hours that Exposure was... None	Low	Mod	High	V High
1	07-Oct-92	M	29	Non-Smoker	None	24	0	0	0	0
2	07-Oct-92	F	57	No Partner	None	24	0	0	0	0
3	07-Oct-92	F	59	No Partner	Mod	22	0	2	0	0
4	07-Oct-92	F	25	No Partner	Low	23	1	0	0	0
5	07-Oct-92	F	56	No Partner	Mod	22.25	0	1.75	0	0
7	08-Oct-92	F	27	Non-Smoker	Mod	12	2	10	0	0
8	08-Oct-92	F	56	Smoker	Mod	0	0	24	0	0
9	08-Oct-92	M	26	Smoker	Mod	18	3	3	0	0
10	08-Oct-92	M	28	Non-Smoker	Low	20	1	0	3	0
12	09-Oct-92	M	29	Non-Smoker	Low	22	0	2	0	0
13	09-Oct-92	F	39	Non-Smoker	Low	21	0	1	2	0
14	09-Oct-92	M	33	Non-Smoker	None	24	0	0	0	0
15	09-Oct-92	M	47	No Partner	Low	24	0	0	0	0
16	09-Oct-92	M	23	Smoker	V High	16	0	0	3	5
17	10-Oct-92	F	36	Non-Smoker	Low	23	1	0	0	0
18	10-Oct-92	M	30	Non-Smoker	None	24	0	0	0	0
19	10-Oct-92	F	22	Non-Smoker	Low	23	0	1	0	0

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 2 (continued)

MONITORING DATE, PERSONAL DETAILS, EXPOSURE TIME AND RATING FOR ALL SUBJECTS

Sub No	Monitoring Date	Sex	Age (years)	Partner "status"	Overall rating of Exposure	Overall Estimate of Hours that Exposure was... None	Low	Mod	High	V High
20	10-Oct-92	F	44	Smoker	Mod	19	1	4	0	0
22	11-Oct-92	F	25	No Partner	Mod	21.5	2	0.5	0	0
23	11-Oct-92	F	38	No Partner	Mod	14	0	2	6	2
24	11-Oct-92	M	27	Smoker	Mod	11	3	8	2	0
25	11-Oct-92	F	36	Smoker	Low	17	5	2	0	0
26	11-Oct-92	F	56	Smoker	Low	23	0	1	0	0
27	12-Oct-92	F	51	Non-Smoker	None	24	0	0	0	0
28	12-Oct-92	M	22	No Partner	None	24	0	0	0	0
29	12-Oct-92	F	40	Smoker	None	24	0	0	0	0
30	12-Oct-92	F	25	No Partner	Low	22	2	0	0	0
31	12-Oct-92	M	27	No Partner	Mod	19	0	5	0	0
32	13-Oct-92	F	36	Non-Smoker	None	24	0	0	0	0
33	13-Oct-92	F	48	Smoker	Mod	0	0	5.5	0	0
35	13-Oct-92	M	57	Non-Smoker	None	24	0	0	0	0
36	13-Oct-92	M	51	Non-Smoker	Mod	0	0	3.5	0	0
37	13-Oct-92	M	29	No Partner	None	24	0	0	0	0
39	14-Oct-92	M	25	Smoker	Mod	21	0	3	0	0

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 2 (continued)

MONITORING DATE, PERSONAL DETAILS, EXPOSURE TIME AND RATING FOR ALL SUBJECTS

Sub No	Monitoring Date	Sex	Age (years)	Partner "status"	Overall rating of Exposure	Overall Estimate of Hours that Exposure was... None	Low	Mod	High	V High
40	14-Oct-92	F	45	Non-Smoker	None	24	0	0	0	0
41	14-Oct-92	F	22	Non-Smoker	Mod	16	1	0	5	2
42	14-Oct-92	F	45	Non-Smoker	None	24	0	0	0	0
43	15-Oct-92	M	38	Non-Smoker	Mod	0	0	0.1	0	0
45	15-Oct-92	M	22	No Partner	Low	20	0	4	0	0
46	15-Oct-92	M	28	Non-Smoker	Low	20	4	0	0	0
47	15-Oct-92	M	43	No Partner	None	24	0	0	0	0
48	16-Oct-92	F	49	Non-Smoker	None	24	0	0	0	0
49	16-Oct-92	M	26	Non-Smoker	Low	22	2	0	0	0
51	16-Oct-92	F	25	Non-Smoker	None	24	0	0	0	0
52	16-Oct-92	M	28	Smoker	Mod	21	0	3	0	0
53	17-Oct-92	M	22	No Partner	None	24	0	0	0	0
54	17-Oct-92	M	36	No Partner	None	24	0	0	0	0
55	17-Oct-92	M	34	Non-Smoker	None	24	0	0	0	0
57	17-Oct-92	M	31	Non-Smoker	None	24	0	0	0	0
58	17-Oct-92	F	24	Non-Smoker	Low	23	1	0	0	0
59	18-Oct-92	F	46	Non-Smoker	None	24	0	0	0	0

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 2 (continued)

MONITORING DATE, PERSONAL DETAILS, EXPOSURE TIME AND RATING FOR ALL SUBJECTS

Sub No	Monitoring Date	Sex	Age (years)	Partner "status"	Overall rating of Exposure	Overall Estimate of Hours that Exposure was... None	Low	Mod	High	V High
60	18-Oct-92	M	48	Smoker	None	24	0	0	0	0
61	18-Oct-92	M	44	Non-Smoker	None	24	0	0	0	0
62	18-Oct-92	F	26	Non-Smoker	None	24	0	0	0	0
63	18-Oct-92	F	24	Non-Smoker	Low	23	0	0	1	0
64	19-Oct-92	F	30	No Partner	None	24	0	0	0	0
66	19-Oct-92	F	38	Smoker	None	24	0	0	0	0
67	19-Oct-92	M	29	Smoker	Mod	18	0	5	1	0
68	19-Oct-92	F	35	Non-Smoker	None	24	0	0	0	0
70	20-Oct-92	F	51	Smoker	Low	20	2	2	0	0
71	20-Oct-92	M	24	No Partner	None	24	0	0	0	0
73	20-Oct-92	F	33	Non-Smoker	Low	23.25	0.75	0	0	0
74	20-Oct-92	M	24	Non-Smoker	None	24	0	0	0	0
77	21-Oct-92	F	25	Non-Smoker	None	24	0	0	0	0
78	21-Oct-92	F	32	No Partner	Low	23	1	0	0	0
79	21-Oct-92	M	29	No Partner	None	24	0	0	0	0
80	22-Oct-92	F	28	Non-Smoker	None	24	0	0	0	0
82	22-Oct-92	F	34	Non-Smoker	Low	22.5	0.5	0	0	1

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 2 (continued)

MONITORING DATE, PERSONAL DETAILS, EXPOSURE TIME AND RATING FOR ALL SUBJECTS

Sub No	Monitoring Date	Sex	Age (years)	Partner "status"	Overall rating of Exposure	Overall Estimate of Hours that Exposure was... None	Low	Mod	High	V High
83	22-Oct-92	M	24	No Partner	None	24	0	0	0	0
84	22-Oct-92	M	56	Non-Smoker	None	24	0	0	0	0
85	22-Oct-92	F	37	Non-Smoker	Low	22	2	0	0	0
86	23-Oct-92	M	32	Non-Smoker	None	24	0	0	0	0
87	23-Oct-92	F	27	Non-Smoker	Low	15	9	0	0	0
88	23-Oct-92	M	37	Smoker	Low	23.75	0	0	0.17	0.08
89	23-Oct-92	M	37	Non-Smoker	Mod	0	21.5	0.5	0	2
90	23-Oct-92	F	43	Smoker	High	21	0	0	3	0
91	24-Oct-92	F	26	Non-Smoker	Low	23	1	0	0	0
92	24-Oct-92	M	43	Non-Smoker	None	24	0	0	0	0
93	24-Oct-92	F	59	No Partner	Low	23.92	0.08	0	0	0
94	24-Oct-92	F	41	No Partner	Low	22	2	0	0	0
95	24-Oct-92	M	23	No Partner	Mod	22.5	0	1.5	0	0
96	25-Oct-92	M	50	Non-Smoker	Low	22	0	2	0	0
97	25-Oct-92	F	50	Non-Smoker	None	24	0	0	0	0
100	25-Oct-92	M	36	Non-Smoker	Low	23	1	0	0	0
101	25-Oct-92	M	39	Smoker	None	24	0	0	0	0

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 2 (continued)

MONITORING DATE, PERSONAL DETAILS, EXPOSURE TIME AND RATING FOR ALL SUBJECTS

Sub No	Monitoring Date	Sex	Age (years)	Partner "status"	Overall rating of Exposure	Overall Estimate of Hours that Exposure was... None	Low	Mod	High	V High
102	26-Oct-92	M	33	Non-Smoker	None	24	0	0	0	0
103	26-Oct-92	M	43	Non-Smoker	Low	23.5	0.5	0	0	0
104	26-Oct-92	F	38	Non-Smoker	None	24	0	0	0	0
105	26-Oct-92	F	30	Smoker	Low	19	0	5	0	0
106	26-Oct-92	F	29	Smoker	Low	22	0	2	0	0
107	27-Oct-92	F	27	Non-Smoker	None	24	0	0	0	0
108	27-Oct-92	F	27	Non-Smoker	Low	21	0	3	0	0
109	27-Oct-92	F	25	Non-Smoker	Mod	23	0	1	0	0
112	27-Oct-92	F	33	No Partner	None	24	0	0	0	0
113	28-Oct-92	M	39	Non-Smoker	Low	21	0	3	0	0
114	28-Oct-92	F	23	Non-Smoker	Low	21	0	3	0	0
115	28-Oct-92	M	52	Non-Smoker	None	24	0	0	0	0
118	29-Oct-92	M	28	Smoker	Mod	8	8	8	0	0
119	29-Oct-92	M	27	No Partner	Low	22	2	0	0	0
120	29-Oct-92	M	26	No Partner	Low	23.87	0.13	0	0	0
121	29-Oct-92	F	50	Smoker	High	9	7.5	7.5	0	0
122	29-Oct-92	F	61	No Partner	Low	23.25	0.75	0	0	0

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 2 (continued)

MONITORING DATE, PERSONAL DETAILS, EXPOSURE TIME AND RATING FOR ALL SUBJECTS

Sub No	Monitoring Date	Sex	Age (years)	Partner "status"	Overall rating of Exposure	Overall Estimate of Hours that Exposure was... None	Low	Mod	High	V High
123	29-Oct-92	F	22	Non-Smoker	Low	23.5	0	0.5	0	0
135	01-Nov-92	M	26	Non-Smoker	Low	22	0	2	0	0
137	01-Nov-92	M	37	Non-Smoker	None	24	0	0	0	0
138	01-Nov-92	F	27	Non-Smoker	None	24	0	0	0	0
139	01-Nov-92	M	32	Non-Smoker	None	24	0	0	0	0
145	03-Nov-92	F	54	Non-Smoker	None	24	0	0	0	0
146	03-Nov-92	F	25	No Partner	Low	23	1	0	0	0
147	03-Nov-92	F	58	No Partner	Low	23.5	0.5	0	0	0
148	03-Nov-92	F	29	Smoker	Mod	10	8	6	0	0
150	03-Nov-92	F	29	Non-Smoker	Low	22	2	0	0	0
151	05-Nov-92	F	22	Non-Smoker	Low	23	1	0	0	0
152	05-Nov-92	F	27	Non-Smoker	Low	23	1	0	0	0
153	05-Nov-92	F	39	Non-Smoker	None	24	0	0	0	0
154	05-Nov-92	M	24	Non-Smoker	None	24	0	0	0	0
155	05-Nov-92	F	25	Non-Smoker	Low	23	1	0	0	0
156	06-Nov-92	M	34	No Partner	None	24	0	0	0	0
157	06-Nov-92	M	28	Non-Smoker	Low	23	1	0	0	0

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2023686568

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 2 (continued)

MONITORING DATE, PERSONAL DETAILS, EXPOSURE TIME AND RATING FOR ALL SUBJECTS

Sub No	Monitoring Date	Sex	Age (years)	Partner "status"	Overall rating of Exposure	Overall Estimate of Hours that Exposure was... None	Low	Mod	High	V High
159	06-Nov-92	M	29	Smoker	None	24	0	0	0	0
166	02-Nov-92	F	27	Non-Smoker	None	24	0	0	0	0
168	08-Nov-92	F	33	Smoker	Mod	3.5	9	10	0.5	1
169	08-Nov-92	M	23	Smoker	Mod	8	15	1	0	0
170	08-Nov-92	F	37	Non-Smoker	Low	22	1	1	0	0
171	08-Nov-92	M	22	No Partner	None	24	0	0	0	0
172	08-Nov-92	M	23	No Partner	None	24	0	0	0	0
173	09-Nov-92	F	40	No Partner	Low	19	0	0	5	0
174	09-Nov-92	F	54	Non-Smoker	None	24	0	0	0	0
175	09-Nov-92	F	26	No Partner	Low	20	4	0	0	0
176	09-Nov-92	F	36	Non-Smoker	Low	23	1	0	0	0
177	09-Nov-92	M	22	Non-Smoker	Low	23	1	0	0	0
178	10-Nov-92	F	58	No Partner	None	24	0	0	0	0
179	10-Nov-92	F	28	Non-Smoker	High	16	0	0	0	8
180	10-Nov-92	M	29	No Partner	Low	23.67	0.33	0	0	0
181	10-Nov-92	F	22	No Partner	Mod	22.5	0.25	0.25	1	0
182	10-Nov-92	M	31	Smoker	High	14.5	0	0	9.5	0

HUK Study no 12/64

2023686569

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 2 (continued)

MONITORING DATE, PERSONAL DETAILS, EXPOSURE TIME AND RATING FOR ALL SUBJECTS

Sub No	Monitoring Date	Sex	Age (years)	Partner "status"	Overall rating of Exposure	Overall Estimate of Hours that Exposure was... None	Low	Mod	High	V High
183	10-Nov-92	F	56	No Partner	None	24	0	0	0	0
184	11-Nov-92	M	26	No Partner	Low	23	1	0	0	0
185	11-Nov-92	F	29	Non-Smoker	Low	23.5	0.5	0	0	0
186	11-Nov-92	F	36	Non-Smoker	Low	23.5	0.5	0	0	0
187	11-Nov-92	M	46	Non-Smoker	Low	16	8	0	0	0
188	11-Nov-92	F	44	Non-Smoker	None	24	0	0	0	0
189	11-Nov-92	F	33	Non-Smoker	None	24	0	0	0	0
190	12-Nov-92	M	41	No Partner	Low	22	2	0	0	0
191	12-Nov-92	F	36	Non-Smoker	Mod	16	0	0	8	0
192	12-Nov-92	M	33	Non-Smoker	Mod	21.8	0.2	2	0	0
193	12-Nov-92	F	30	Non-Smoker	Low	23.8	0.2	0	0	0
194	12-Nov-92	M	24	Smoker	Low	23	0.25	0.75	0	0
195	12-Nov-92	M	54	Non-Smoker	Low	23.33	0.67	0	0	0
196	13-Nov-92	F	42	Non-Smoker	None	24	0	0	0	0
197	13-Nov-92	F	26	Smoker	Low	23	1	0	0	0
198	13-Nov-92	F	55	Non-Smoker	None	24	0	0	0	0
199	13-Nov-92	M	58	Non-Smoker	Low	22	2	0	0	0

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 2 (continued)

MONITORING DATE, PERSONAL DETAILS, EXPOSURE TIME AND RATING FOR ALL SUBJECTS

Sub No	Monitoring Date	Sex	Age (years)	Partner "status"	Overall rating of Exposure	Overall Estimate of Hours that Exposure was... None	Low	Mod	High	V High
200	13-Nov-92	M	46	Non-Smoker	Low	23.5	0.5	0	0	0
201	13-Nov-92	F	43	Non-Smoker	Low	23	1	0	0	0
202	14-Nov-92	F	26	Non-Smoker	High	17	0	1	2	4
203	14-Nov-92	F	26	No Partner	Low	23.8	0.2	0	0	0
204	14-Nov-92	F	34	No Partner	None	24	0	0	0	0
205	14-Nov-92	M	26	No Partner	Low	20.5	0	0	0	3.5
206	14-Nov-92	F	27	No Partner	Low	23.25	0	0	0.5	0.25
207	14-Nov-92	M	31	No Partner	Low	22	2	0	0	0
208	15-Nov-92	M	26	Non-Smoker	Low	22	2	0	0	0
209	15-Nov-92	F	40	Non-Smoker	None	24	0	0	0	0
210	15-Nov-92	M	23	No Partner	Low	21	0	3	0	0
214	16-Nov-92	M	44	Non-Smoker	None	24	0	0	0	0
215	16-Nov-92	M	47	Smoker	Mod	20	1	1	2	0
216	16-Nov-92	F	32	Smoker	High	13	0	8	2	1
219	16-Nov-92	F	33	No Partner	Low	22.5	1.5	0	0	0
220	17-Nov-92	M	41	Non-Smoker	None	24	0	0	0	0
221	17-Nov-92	F	56	Non-Smoker	None	24	0	0	0	0

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 2 (continued)

MONITORING DATE, PERSONAL DETAILS, EXPOSURE TIME AND RATING FOR ALL SUBJECTS

Sub No	Monitoring Date	Sex	Age (years)	Partner "status"	Overall rating of Exposure	Overall Estimate of Hours that Exposure was... None	Low	Mod	High	V High
222	17-Nov-92	M	36	Non-Smoker	Low	22	2	0	0	0
223	17-Nov-92	F	24	No Partner	Low	23	0	1	0	0
224	17-Nov-92	M	45	Non-Smoker	None	24	0	0	0	0
225	19-Nov-92	M	29	Non-Smoker	None	24	0	0	0	0
226	19-Nov-92	M	24	No Partner	Low	20	4	0	0	0
227	19-Nov-92	M	22	No Partner	Low	23.5	0.5	0	0	0
228	19-Nov-92	F	35	Non-Smoker	Low	23	1	0	0	0
229	19-Nov-92	F	44	Non-Smoker	None	24	0	0	0	0
230	20-Nov-92	F	32	Non-Smoker	Mod	22	0.5	1.5	0	0
232	20-Nov-92	F	26	Non-Smoker	None	24	0	0	0	0
233	20-Nov-92	F	28	No Partner	Mod	15	1	6	1	1
234	20-Nov-92	F	24	Non-Smoker	Mod	13	0	0	10	1
235	21-Nov-92	F	57	Non-Smoker	None	24	0	0	0	0
236	21-Nov-92	M	26	Non-Smoker	Low	23	1	0	0	0
237	21-Nov-92	F	28	Smoker	Low	0	24	0	0	0
238	21-Nov-92	M	36	Non-Smoker	Low	22	2	0	0	0
239	21-Nov-92	F	24	No Partner	Low	23.5	0.5	0	0	0

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 2 (continued)

MONITORING DATE, PERSONAL DETAILS, EXPOSURE TIME AND RATING FOR ALL SUBJECTS

Sub No	Monitoring Date	Sex	Age (years)	Partner "status"	Overall rating of Exposure	Overall Estimate of Hours that Exposure was... None	Low	Mod	High	V High
240	22-Nov-92	F	46	Non-Smoker	None	24	0	0	0	0
241	22-Nov-92	M	25	No Partner	Low	22	2	0	0	0
242	22-Nov-92	F	27	No Partner	None	24	0	0	0	0
243	22-Nov-92	M	36	Smoker	Low	21	2	0	0	1
244	22-Nov-92	F	57	Non-Smoker	Low	23	1	0	0	0
245	22-Nov-92	F	24	Non-Smoker	None	24	0	0	0	0
246	23-Nov-92	M	21	No Partner	Low	23.5	0.5	0	0	0
247	23-Nov-92	F	27	Non-Smoker	None	24	0	0	0	0
248	23-Nov-92	F	48	Non-Smoker	None	24	0	0	0	0
249	23-Nov-92	M	47	Non-Smoker	None	24	0	0	0	0
251	23-Nov-92	F	56	Non-Smoker	Low	23.8	0.2	0	0	0
255	24-Nov-92	M	30	No Partner	None	24	0	0	0	0
256	24-Nov-92	F	58	Non-Smoker	None	24	0	0	0	0
257	25-Nov-92	F	25	Non-Smoker	Mod	22	0	0	0.5	1.5
260	25-Nov-92	F	25	Non-Smoker	None	24	0	0	0	0
262	25-Nov-92	F	30	Smoker	Low	23	1	0	0	0
263	26-Nov-92	F	44	No Partner	High	8	3	2	9	0

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 2 (continued)

MONITORING DATE, PERSONAL DETAILS, EXPOSURE TIME AND RATING FOR ALL SUBJECTS

Sub No	Monitoring Date	Sex	Age (years)	Partner "status"	Overall rating of Exposure	Overall Estimate of Hours that Exposure was... None	Low	Mod	High	V High
264	26-Nov-92	M	57	Non-Smoker	Mod	17	0	7	0	0
265	26-Nov-92	M	53	Non-Smoker	None	24	0	0	0	0
266	26-Nov-92	F	55	No Partner	Low	23	1	0	0	0
267	26-Nov-92	F	52	Non-Smoker	None	24	0	0	0	0
268	27-Nov-92	F	36	Smoker	None	24	0	0	0	0
269	27-Nov-92	M	26	Non-Smoker	None	24	0	0	0	0
271	27-Nov-92	F	27	No Partner	None	24	0	0	0	0
272	27-Nov-92	F	27	Non-Smoker	None	24	0	0	0	0
273	28-Nov-92	F	56	Non-Smoker	Low	18	6	0	0	0
274	28-Nov-92	F	59	No Partner	Low	22	2	0	0	0
275	28-Nov-92	M	58	Smoker	None	24	0	0	0	0
276	28-Nov-92	F	51	No Partner	Low	23.9	0.1	0	0	0
277	28-Nov-92	F	22	Smoker	High	8	7	5	2	2
279	28-Nov-92	F	21	Smoker	Mod	20	0	4	0	0
280	29-Nov-92	M	26	Non-Smoker	Low	21	3	0	0	0
281	29-Nov-92	M	35	Non-Smoker	None	24	0	0	0	0
282	29-Nov-92	M	46	Smoker	Mod	15	8	0	0	1

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 2 (continued)

MONITORING DATE, PERSONAL DETAILS, EXPOSURE TIME AND RATING FOR ALL SUBJECTS

Sub No	Monitoring Date	Sex	Age (years)	Partner "status"	Overall rating of Exposure	Overall Estimate of Hours that Exposure was... None	Low	Mod	High	V High
283	29-Nov-92	F	38	No Partner	Mod	21.5	0	1	1.5	0
284	29-Nov-92	F	30	No Partner	Mod	23	0	1	0	0
285	30-Nov-92	M	59	Non-Smoker	None	24	0	0	0	0
286	30-Nov-92	F	58	No Partner	None	24	0	0	0	0
287	30-Nov-92	F	55	No Partner	Low	23.5	0	0.5	0	0
288	30-Nov-92	F	25	No Partner	None	24	0	0	0	0
289	30-Nov-92	M	38	Non-Smoker	High	16	0	1	2	5
290	01-Dec-92	F	52	Smoker	Mod	23	0	1	0	0
292	01-Dec-92	M	26	Non-Smoker	Mod	18	1	3	2	0
293	01-Dec-92	F	23	Non-Smoker	Low	23.5	0.5	0	0	0
295	02-Dec-92	M	24	Smoker	High	12	8	0	4	0
296	02-Dec-92	F	55	Smoker	Mod	23.5	0	0.5	0	0
297	02-Dec-92	F	53	No Partner	Low	23	1	0	0	0
298	02-Dec-92	F	47	Non-Smoker	None	24	0	0	0	0
299	02-Dec-92	F	60	No Partner	None	24	0	0	0	0
302	03-Dec-92	M	34	Smoker	Mod	22	0.5	0.5	0	1
303	03-Dec-92	F	37	Non-Smoker	None	24	0	0	0	0

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 2 (continued)

MONITORING DATE, PERSONAL DETAILS, EXPOSURE TIME AND RATING FOR ALL SUBJECTS

Sub No	Monitoring Date	Sex	Age (years)	Partner "status"	Overall rating of Exposure	Overall Estimate of Hours that Exposure was... None	Low	Mod	High	V High
304	03-Dec-92	F	35	Non-Smoker	None	24	0	0	0	0
305	03-Dec-92	F	40	Non-Smoker	Low	22	2	0	0	0
311	08-Dec-92	M	24	No Partner	Low	21	0	3	0	0
312	08-Dec-92	M	44	Non-Smoker	None	24	0	0	0	0
313	08-Dec-92	M	55	Smoker	None	24	0	0	0	0
314	08-Dec-92	F	23	No Partner	Low	21	3	0	0	0
315	08-Dec-92	F	26	Smoker	Low	23.5	0.5	0	0	0
316	08-Dec-92	M	25	No Partner	None	24	0	0	0	0
317	09-Dec-92	M	24	Smoker	Low	22.5	1.5	0	0	0
318	09-Dec-92	F	27	Smoker	Mod	17	3	4	0	0
319	09-Dec-92	F	30	Smoker	Low	18	2	3	0	1
320	09-Dec-92	M	23	No Partner	Low	23	1	0	0	0
321	09-Dec-92	M	22	No Partner	Low	21	3	0	0	0
322	11-Dec-92	M	26	No Partner	None	24	0	0	0	0
323	11-Dec-92	F	35	Non-Smoker	Low	21	0	2	0.5	0.5
324	11-Dec-92	F	37	Non-Smoker	None	24	0	0	0	0
327	11-Dec-92	F	22	Non-Smoker	Low	23.5	0	0	0.5	0

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APPENDIX 6.3

PERCENT EXPOSURE, OVERALL RATING AND TIME SPENT BY ACTIVITY

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 3

PERCENT EXPOSURE, OVERALL RATING AND TIME SPENT FOR ALL SUBJECTS BY ACTIVITY

Sub	Exposure at Home			Exposure at Work			Exposure at Leisure			Exposure during Travel		
No	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours
1	0%	None	21	0%	No Data	0	0%	No Data	0	0%	None	3
2	0%	None	21	0%	No Data	0	0%	None	2.67	0%	None	0.33
3	100%	Moderate	23	0%	No Data	0	0%	None	0	0%	None	1
4	100%	Low	16	0%	None	7	0%	No Data	0	0%	None	1
5	0%	None	20.5	0%	No Data	0	100%	Very Low	1.5	0%	None	0.5
7	20%	Very Low	15.5	80%	Moderate	8	0%	No Data	0	0%	None	0.5
8	100%	Moderate	21.5	0%	No Data	0	0%	None	2	0%	None	0.5
9	10%	Low	11.5	10%	Low	8.5	80%	High	2	0%	None	2
10	0%	None	12	25%	Low	7.5	75%	Moderate	3	0%	None	1.5
12	0%	None	6	0%	None	10	100%	Moderate	3	0%	Low	4.5
13	0%	None	16	0%	None	5	100%	Moderate	2	0%	None	1
14	0%	None	13.5	0%	None	10	0%	None	0	0%	None	0.5
15	0%	None	21.75	0%	No Data	0	0%	Very Low	2	100%	None	0.25
16	10%	Low	8	80%	Low	10	10%	High	4	0%	None	2
17	0%	None	19	0%	No Data	0	100%	High	4	0%	None	1
18	0%	None	21	0%	No Data	0	0%	None	2.5	0%	None	0.5
19	0%	None	13.5	0%	None	1	100%	None	8	0%	None	1.5

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 3 (continued)

PERCENT EXPOSURE, OVERALL RATING AND TIME SPENT FOR ALL SUBJECTS BY ACTIVITY

Sub	Exposure at Home			Exposure at Work			Exposure at Leisure			Exposure during Travel		
No	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours
20	67%	Very High	16.5	0%	None	1	33%	Moderate	5	0%	None	1.5
22	100%	Moderate	23	0%	No Data	0	0%	None	0	0%	Low	1
23	0%	None	8	80%	Very High	11	10%	High	3	10%	None	2
24	35%	High	14	30%	Moderate	3	25%	Moderate	5	10%	Moderate	2
25	100%	Moderate	22.5	0%	No Data	0	0%	None	0	0%	None	1.5
26	0%	None	22.5	0%	No Data	0	0%	Very Low	0	100%	Low	1.5
27	0%	None	22	0%	No Data	0	0%	None	2	0%	No Data	0
28	0%	None	16	0%	No Data	0	0%	None	4	0%	None	4
29	0%	None	14.75	0%	Very Low	8	0%	None	1	0%	None	0.25
30	100%	Low	16	0%	None	4	0%	None	4	0%	No Data	0
31	0%	None	18.5	100%	Moderate	5	0%	No Data	0	0%	None	0.5
32	0%	None	17	0%	None	2	0%	None	4	0%	None	1
33	100%	Moderate	18.5	0%	None	3.5	0%	None	1	0%	None	1
35	0%	None	20	0%	No Data	0	0%	None	3.5	0%	None	0.5
36	0%	None	19.75	0%	No Data	0	100%	Low	3.5	0%	None	0.75
37	0%	None	22.25	0%	No Data	0	0%	Very Low	1	0%	None	0.75
39	10%	Very Low	10	30%	Low	8	30%	Low	2	30%	Very Low	4

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 3 (continued)

PERCENT EXPOSURE, OVERALL RATING AND TIME SPENT FOR ALL SUBJECTS BY ACTIVITY

Sub	Exposure at Home			Exposure at Work			Exposure at Leisure			Exposure during Travel		
No	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours
40	0%	None	14.5	0%	None	7.5	0%	None	0.5	0%	None	1.5
41	0%	None	13	100%	Very High	9	0%	None	1	0%	None	1
42	0%	None	22	0%	No Data	0	0%	None	0	0%	None	2
43	0%	None	21	0%	No Data	0	100%	Moderate	1	0%	None	2
45	0%	None	17	0%	No Data	0	70%	Moderate	5.5	30%	High	1.5
46	0%	None	15	0%	No Data	0	100%	Low	4	0%	None	5
47	0%	None	21	0%	No Data	0	0%	None	2	0%	None	1
48	0%	None	13	0%	None	8	0%	None	0.75	0%	None	2.25
49	0%	None	12	25%	Very Low	8	75%	Moderate	2.5	0%	None	1.5
51	0%	None	19.5	0%	No Data	0	0%	None	4	0%	None	0.5
52	0%	Low	17	0%	No Data	0	100%	High	5.33	0%	None	1.67
53	0%	None	24	0%	No Data	0	0%	No Data	0	0%	No Data	0
54	0%	None	22	0%	No Data	0	0%	None	1	0%	None	1
55	0%	None	18	0%	No Data	0	0%	None	2	0%	None	4
57	0%	Very Low	16	0%	None	7	0%	No Data	0	0%	None	1
58	0%	None	21	0%	No Data	0	0%	Very Low	3	100%	None	0
59	0%	None	23.5	0%	No Data	0	0%	None	0	0%	None	0.5

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 3 (continued)

PERCENT EXPOSURE, OVERALL RATING AND TIME SPENT FOR ALL SUBJECTS BY ACTIVITY

Sub	Exposure at Home			Exposure at Work			Exposure at Leisure			Exposure during Travel		
No	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours
60	0%	None	20.5	0%	No Data	0	0%	None	2.5	0%	None	1
61	0%	None	23.5	0%	No Data	0	0%	No Data	0	0%	None	0.5
62	0%	None	21.5	0%	No Data	0	0%	None	2	0%	None	0.5
63	100%	Very Low	24	0%	No Data	0	0%	No Data	0	0%	No Data	0
64	0%	None	17.5	0%	No Data	0	0%	None	3	0%	None	3.5
66	0%	Very Low	23.25	0%	No Data	0	0%	No Data	0	0%	None	0.75
67	100%	Moderate	23	0%	No Data	0	0%	No Data	0	0%	None	1
68	0%	None	24	0%	No Data	0	0%	No Data	0	0%	No Data	0
70	100%	Low	14.5	0%	None	8	0%	None	0.5	0%	None	1
71	. 0%	None	15.75	0%	None	8	0%	No Data	0	0%	None	0.25
73	0%	None	10.5	100%	Very Low	8	0%	None	4	0%	None	1.5
74	0%	Very Low	15.75	0%	Very Low	8	0%	No Data	0	0%	None	0.25
77	0%	None	13	0%	None	8	0%	Very Low	1	0%	None	2
78	100%	None	22	0%	No Data	0	0%	None	1.5	0%	None	0.5
79	0%	None	14	0%	No Data	0	0%	High	4	0%	Very Low	6
80	0%	None	19.5	0%	None	4	0%	None	0.25	0%	None	0.25
82	0%	None	13	60%	Very Low	7.5	40%	High	2	0%	None	1.5

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 3 (continued)

PERCENT EXPOSURE, OVERALL RATING AND TIME SPENT FOR ALL SUBJECTS BY ACTIVITY

Sub	Exposure at Home			Exposure at Work			Exposure at Leisure			Exposure during Travel		
No	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours
83	0%	None	13.5	0%	None	8	0%	No Data	0	0%	None	0.5
84	0%	None	19.5	0%	No Data	0	0%	None	3.5	0%	None	1
85	0%	None	21.5	0%	No Data	0	100%	Moderate	2	0%	None	0.5
86	0%	None	21.5	0%	No Data	0	0%	None	1.5	0%	None	1
87	100%	Low	19	0%	No Data	0	0%	Very Low	3.5	0%	None	1.5
88	80%	Very Low	15.66	3%	Very Low	8	0%	No Data	0	17%	Low	0.34
89	20%	Very Low	19.5	0%	No Data	0	80%	Very High	3.5	0%	None	1
90	100%	Moderate	12.75	0%	None	9.25	0%	No Data	0	0%	None	2
91	0%	None	16.5	40%	Low	3	60%	Low	3.5	0%	None	1
92	0%	None	21.75	0%	No Data	0	0%	None	1.5	0%	None	0.75
93	0%	None	17.5	100%	Moderate	2.5	0%	None	3.5	0%	None	0.5
94	0%	None	18.75	100%	Low	3	0%	None	2	0%	None	0.25
95	0%	None	19	0%	No Data	0	100%	Moderate	5	0%	Very Low	0
96	0%	Very Low	21	0%	No Data	0	100%	Moderate	2	0%	None	1
97	0%	None	22	0%	No Data	0	0%	None	1	0%	None	1
100	100%	Moderate	24	0%	No Data	0	0%	No Data	0	0%	No Data	0
101	0%	None	20	0%	No Data	0	0%	None	3	0%	None	1

HUK Study no 12/64

2023686582

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 3 (continued)

PERCENT EXPOSURE, OVERALL RATING AND TIME SPENT FOR ALL SUBJECTS BY ACTIVITY

Sub	Exposure at Home			Exposure at Work			Exposure at Leisure			Exposure during Travel		
No	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours
102	0%	None	18	0%	None	4	0%	No Data	0	0%	None	2
103	0%	None	16	0%	None	5	100%	Very Low	2	0%	None	1
104	0%	None	19	0%	None	2	0%	None	2	0%	None	1
105	100%	Moderate	16	0%	None	6.5	0%	None	1	0%	None	0.5
106	0%	None	20	0%	No Data	0	100%	Moderate	3	0%	None	1
107	0%	None	19.5	0%	No Data	0	0%	None	3	0%	None	1.5
108	0%	None	19	90%	Moderate	3	0%	Moderate	0	10%	Low	2
109	0%	None	22	0%	No Data	0	100%	Moderate	1	0%	None	1
112	0%	None	16.75	0%	None	4.5	0%	None	2	0%	None	0.75
113	0%	None	15.5	100%	Moderate	8	0%	No Data	0	0%	None	0.5
114	0%	None	10	20%	Very Low	9	80%	Low	3	0%	None	2
115	0%	None	18.75	0%	None	4.5	0%	No Data	0	0%	None	0.75
118	30%	Very Low	16.5	70%	Low	7	0%	No Data	0	0%	None	0.5
119	0%	None	20	50%	None	3.5	0%	No Data	0	50%	None	0.5
120	100%	Very Low	22.66	0%	No Data	0	0%	None	1	0%	None	0.34
121	60%	Moderate	17.67	0%	No Data	0	30%	Moderate	6	10%	Low	0.33
122	100%	Low	21	0%	No Data	0	0%	Very Low	1.5	0%	None	1.5

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2023686583

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 3 (continued)

PERCENT EXPOSURE, OVERALL RATING AND TIME SPENT FOR ALL SUBJECTS BY ACTIVITY

Sub	Exposure at Home			Exposure at Work			Exposure at Leisure			Exposure during Travel		
No	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours
123	0%	None	12.5	0%	None	9.5	0%	No Data	0	100%	Very Low	2
135	0%	None	19	0%	No Data	0	100%	Moderate	4	0%	None	1
137	0%	None	23	0%	No Data	0	0%	No Data	0	0%	None	1
138	0%	None	20	0%	No Data	0	0%	Very Low	3	0%	None	1
139	0%	None	19	0%	No Data	0	0%	None	4	0%	None	1
145	0%	None	18	0%	None	4	0%	None	1	0%	None	1
146	0%	None	14	100%	Low	5.5	0%	None	3	0%	None	1.5
147	0%	None	23.5	0%	No Data	0	100%	Very Low	0.25	0%	None	0.25
148	50%	Moderate	16	50%	High	6	0%	None	0.5	0%	None	1.5
150	100%	Moderate	21.5	0%	No Data	0	0%	None	2	0%	None	0.5
151	0%	None	15	100%	Very Low	7	0%	None	1	0%	None	1
152	50%	Low	16	50%	Low	6	0%	None	1	0%	None	1
153	0%	None	19.5	0%	No Data	0	0%	None	3	0%	None	1.5
154	0%	None	18	0%	None	5	0%	None	0	0%	None	1
155	0%	None	15.5	100%	Low	8	0%	No Data	0	0%	None	0.5
156	0%	None	16.5	0%	None	3	0%	None	2	0%	None	2.5
157	0%	None	20.5	0%	No Data	0	100%	Low	3	0%	None	0.5

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 3 (continued)

PERCENT EXPOSURE, OVERALL RATING AND TIME SPENT FOR ALL SUBJECTS BY ACTIVITY

Sub	Exposure at Home			Exposure at Work			Exposure at Leisure			Exposure during Travel		
No	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours
159	0%	None	11.75	0%	No Data	0	0%	None	12	0%	None	0.25
166	0%	None	19.5	0%	No Data	0	0%	None	3	0%	None	1.5
168	60%	Moderate	22.25	0%	No Data	0	40%	None	0.75	0%	None	1
169	90%	Moderate	23	0%	No Data	0	0%	None	0	10%	High	1
170	0%	None	19.33	0%	No Data	0	100%	Very Low	4	0%	None	0.67
171	0%	None	23.25	0%	No Data	0	0%	None	0	0%	None	0.75
172	0%	None	16.5	0%	No Data	0	0%	None	7	0%	None	0.5
173	0%	None	19	100%	Very High	4.8	0%	No Data	0	0%	None	0.2
174	0%	None	15.9	0%	None	8	0%	No Data	0	0%	None	0.1
175	0%	None	12	100%	Very Low	11	0%	None	0	0%	None	1
176	0%	None	23	0%	No Data	0	100%	Moderate	0.8	0%	None	0.2
177	0%	None	14	5%	Very High	7	95%	Moderate	3	0%	None	0
178	0%	None	23	0%	No Data	0	0%	None	0	0%	None	1
179	0%	None	14.5	100%	Very High	8	0%	No Data	0	0%	None	1.5
180	0%	None	21.75	0%	No Data	0	0%	None	0.75	100%	Very Low	1.5
181	0%	None	17.33	80%	High	5	0%	No Data	0	20%	Moderate	0.67
182	100%	High	23.5	0%	No Data	0	0%	No Data	0	0%	None	0.5

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 3 (continued)

PERCENT EXPOSURE, OVERALL RATING AND TIME SPENT FOR ALL SUBJECTS BY ACTIVITY

Sub	Exposure at Home			Exposure at Work			Exposure at Leisure			Exposure during Travel		
No	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours
183	0%	None	15.75	0%	None	6	0%	None	1	0%	None	1.25
184	0%	None	20	0%	No Data	0	100%	Low	3	0%	None	1
185	0%	None	12.5	100%	Very Low	11	0%	No Data	0	0%	None	0.5
186	0%	None	15.25	100%	Very Low	8.5	0%	No Data	0	0%	None	0.25
187	0%	None	11	100%	High	12	0%	No Data	0	0%	None	1
188	0%	None	24	0%	No Data	0	0%	No Data	0	0%	None	0
189	0%	None	23	0%	No Data	0	0%	No Data	0	0%	None	1
190	0%	None	8	0%	None	2	100%	Very Low	10	0%	None	4
191	0%	None	14.5	100%	Very High	8	0%	No Data	0	0%	None	1.5
192	1%	Moderate	12	80%	Moderate	8	19%	Low	1	0%	None	3
193	0%	Very Low	16	0%	No Data	0	0%	Very Low	3	100%	None	5
194	100%	Low	20.6	0%	None	3	0%	No Data	0	0%	None	0.4
195	0%	Very Low	16	0%	None	6	100%	Very Low	1	0%	None	1
196	0%	None	22	0%	None	1.75	0%	No Data	0	0%	None	0.25
197	100%	Moderate	13.75	0%	None	9	0%	No Data	0	0%	None	0.25
198	0%	None	24	0%	No Data	0	0%	No Data	0	0%	No Data	0
199	0%	None	16	0%	None	3	100%	Low	3	0%	None	2

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 3 (continued)

PERCENT EXPOSURE, OVERALL RATING AND TIME SPENT FOR ALL SUBJECTS BY ACTIVITY

Sub	Exposure at Home			Exposure at Work			Exposure at Leisure			Exposure during Travel		
No	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours
200	100%	Low	19.5	0%	None	1.5	0%	No Data	0	0%	None	3
201	0%	None	15	100%	Low	8	0%	No Data	0	0%	None	1
202	0%	None	16	98%	Very High	4	2%	Very Low	3	0%	None	1
203	0%	None	22.5	0%	No Data	0	100%	None	1.5	0%	Very Low	0
204	0%	None	22.5	0%	No Data	0	0%	None	1	0%	None	0.5
205	0%	None	13	0%	None	5	100%	Very High	5	0%	None	1
206	0%	None	17	100%	Very High	4	0%	None	0.5	0%	None	2.5
207	90%	None	22.5	0%	No Data	0	5%	Low	1	5%	Low	0.5
208	0%	None	17.5	0%	No Data	0	100%	Very Low	5	0%	None	1.5
209	0%	None	19.5	0%	No Data	0	0%	None	2.5	0%	None	2
210	0%	None	15	0%	No Data	0	100%	Moderate	4	0%	None	5
214	0%	None	22	0%	No Data	0	0%	None	1	0%	None	1
215	70%	High	20	0%	No Data	0	10%	None	2	20%	None	2
216	0%	None	12	100%	High	11	0%	No Data	0	0%	None	1
219	0%	None	16.5	0%	No Data	0	100%	Very Low	6	0%	None	1.5
220	0%	None	14	0%	None	8	0%	None	1	0%	None	1
221	0%	None	21	0%	No Data	0	0%	None	3	0%	None	0

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 3 (continued)

PERCENT EXPOSURE, OVERALL RATING AND TIME SPENT FOR ALL SUBJECTS BY ACTIVITY

Sub	Exposure at Home			Exposure at Work			Exposure at Leisure			Exposure during Travel		
No	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours
222	0%	None	18.5	85%	Very Low	0.75	15%	No Data	0	0%	None	4.25
223	50%	Very Low	21	0%	No Data	0	50%	Very Low	2.5	0%	None	0.5
224	0%	None	15.5	0%	None	8	0%	No Data	0	0%	None	0.5
225	0%	None	21.25	0%	No Data	0	0%	None	2	0%	None	0.75
226	0%	None	9.75	100%	Very Low	14	0%	No Data	0	0%	None	0.25
227	0%	None	10	0%	No Data	0	80%	Very Low	13.5	20%	Very Low	0.5
228	0%	None	18	100%	Low	5	0%	None	0	0%	None	1
229	0%	None	23	0%	No Data	0	0%	Very Low	0.5	0%	None	0.5
230	.0%	None	20	0%	No Data	0	100%	Moderate	2	0%	None	2
232	0%	None	18	0%	No Data	0	0%	None	4	0%	None	2
233	30%	Low	13.5	65%	Moderate	9	0%	No Data	0	5%	None	1.5
234	20%	Low	12	70%	High	11	0%	No Data	0	10%	High	1
235	0%	None	12	0%	None	8	0%	None	3	0%	None	1
236	0%	None	16.25	0%	None	2	100%	Low	5	0%	None	0.75
237	100%	Very Low	16	0%	No Data	0	0%	None	6	0%	None	2
238	0%	None	17	0%	None	3	100%	Moderate	2	0%	None	2
239	25%	Very Low	16	75%	Low	3	0%	None	4.25	0%	None	0.75

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 3 (continued)

PERCENT EXPOSURE, OVERALL RATING AND TIME SPENT FOR ALL SUBJECTS BY ACTIVITY

Sub	Exposure at Home			Exposure at Work			Exposure at Leisure			Exposure during Travel		
No	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours
240	0%	None	22.5	0%	No Data	0	0%	None	1	0%	None	0.5
241	100%	Very Low	23.5	0%	No Data	0	0%	None	0.15	0%	None	0.35
242	0%	None	23	0%	No Data	0	0%	None	1	0%	None	0
243	100%	Moderate	21	0%	No Data	0	0%	Moderate	0.5	0%	None	2.5
244	0%	None	21.5	0%	No Data	0	100%	Low	2	0%	None	0.5
245	0%	None	22	0%	No Data	0	0%	None	1	0%	None	1
246	0%	None	9	100%	Very Low	5	0%	None	9	0%	None	1
247	0%	None	12.25	0%	None	7.5	0%	None	3.5	0%	None	0.75
248	0%	None	17.5	0%	None	6	0%	No Data	0	0%	None	0.5
249	0%	None	17.5	0%	None	4	0%	None	1.5	0%	None	1
251	0%	None	14.5	100%	Very Low	7.5	0%	None	1.5	0%	None	0.5
255	0%	None	19.75	0%	No Data	0	0%	None	3	0%	None	1.25
256	0%	None	20.25	0%	No Data	0	0%	Very Low	2.5	0%	None	0.75
257	0%	None	14.5	100%	High	8	0%	None	0.5	0%	None	1
260	0%	None	13.5	0%	None	8	0%	None	2	0%	None	0.5
262	0%	None	19	100%	Very Low	3	0%	None	1	0%	None	1
263	80%	High	19	0%	No Data	0	20%	Very Low	3	0%	None	2

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 3 (continued)

PERCENT EXPOSURE, OVERALL RATING AND TIME SPENT FOR ALL SUBJECTS BY ACTIVITY

Sub	Exposure at Home			Exposure at Work			Exposure at Leisure			Exposure during Travel		
No	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours
264	0%	None	11	100%	High	7	0%	None	5.5	0%	None	0.5
265	0%	None	23.33	0%	No Data	0	0%	No Data	0	0%	None	0.67
266	0%	None	20	0%	No Data	0	100%	Very Low	3	0%	None	1
267	0%	None	18	0%	No Data	0	0%	None	4	0%	None	2
268	0%	None	15	0%	None	7.5	0%	No Data	0	0%	None	1.5
269	0%	None	16	0%	No Data	0	0%	None	6	0%	None	2
271	0%	None	13.5	0%	None	7	0%	None	3	0%	None	0.5
272	0%	None	13.5	0%	None	7	0%	None	3	0%	None	0.5
273	0%	None	17.67	100%	Very Low	6	0%	No Data	0	0%	None	0.33
274	0%	None	20.5	100%	Very Low	2	0%	Low	1	0%	Very Low	0.5
275	0%	Moderate	21	0%	No Data	0	0%	Low	2	0%	None	1
276	0%	None	20.25	0%	No Data	0	100%	Very Low	2.25	0%	Very Low	1.5
277	0%	Low	15.5	90%	High	6	0%	Very Low	2.5	10%	Low	1
279	100%	Moderate	16.5	0%	No Data	0	0%	None	6.5	0%	Low	1
280	0%	No Data	18	0%	No Data	0	100%	Low	5	0%	None	1
281	0%	None	23	0%	No Data	0	0%	No Data	0	0%	None	1
282	60%	High	15.33	40%	High	8	0%	No Data	0	0%	None	0.67

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 3 (continued)

PERCENT EXPOSURE, OVERALL RATING AND TIME SPENT FOR ALL SUBJECTS BY ACTIVITY

Sub	Exposure at Home			Exposure at Work			Exposure at Leisure			Exposure during Travel		
No	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours
283	0%	None	11	0%	No Data	0	100%	Moderate	10.75	0%	None	2.25
284	0%	None	17.5	0%	No Data	0	100%	Very High	5.5	0%	None	1
285	0%	None	22	0%	No Data	0	0%	None	2	0%	None	0
286	0%	None	20.8	0%	None	2.5	0%	None	0.5	0%	None	0.2
287	0%	None	14	100%	Moderate	8.5	0%	None	0.5	0%	None	1
288	0%	None	23.5	0%	No Data	0	0%	None	0.5	0%	None	0
289	0%	None	13	0%	No Data	0	95%	High	8	5%	Low	3
290	90%	Moderate	16	10%	Very Low	5	0%	Very Low	1.5	0%	None	1.5
292	0%	None	15	100%	High	6.5	0%	None	0.5	0%	Very Low	2
293	0%	None	9.25	100%	Low	8.5	0%	None	5.5	0%	None	0.75
295	100%	Moderate	20.8	0%	No Data	0	0%	Very Low	1.67	0%	High	1.5
296	0%	None	17	100%	Low	5	0%	No Data	0	0%	None	2
297	0%	None	13	100%	Low	10	0%	No Data	0	0%	None	1
298	0%	None	22.8	0%	No Data	0	0%	None	1	0%	None	0.2
299	0%	None	22.75	0%	No Data	0	0%	No Data	0	0%	None	1.25
302	75%	Moderate	12	0%	None	7.5	25%	Very Low	0.5	0%	None	4
303	0%	None	20	0%	No Data	0	0%	None	3.5	0%	None	0.5

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 3 (continued)

PERCENT EXPOSURE, OVERALL RATING AND TIME SPENT FOR ALL SUBJECTS BY ACTIVITY

Sub	Exposure at Home			Exposure at Work			Exposure at Leisure			Exposure during Travel		
No	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours	%	Rating	Hours
304	0%	None	23.33	0%	No Data	0	0%	None	0.17	0%	None	0.5
305	0%	None	21	0%	No Data	0	100%	None	2	0%	None	1
311	80%	Low	18	0%	No Data	0	20%	Very Low	5	0%	Very Low	1
312	0%	None	18	0%	None	6	0%	No Data	0	0%	No Data	0
313	0%	Very Low	22	0%	No Data	0	0%	None	1	0%	None	1
314	0%	None	10.5	100%	Very Low	5	0%	None	7	0%	None	1.5
315	90%	Low	15	10%	None	6.5	0%	No Data	0	0%	None	2.5
316	0%	None	19	0%	None	1.5	0%	Very Low	2.5	0%	None	1
317	100%	Low	23.67	0%	No Data	0	0%	None	0.08	0%	None	0.25
318	70%	Moderate	14.5	10%	Very Low	7.5	20%	Moderate	1.5	0%	None	0.5
319	15%	Very Low	17.67	0%	No Data	0	80%	Moderate	6	5%	High	0.33
320	100%	Low	21	0%	No Data	0	0%	Very Low	2	0%	None	1
321	0%	Low	19.5	0%	No Data	0	100%	Low	3	0%	None	1.5
322	0%	Very Low	23.85	0%	No Data	0	0%	None	0.05	0%	None	0.1
323	0%	None	18.5	0%	No Data	0	95%	Moderate	4	5%	None	1.5
324	0%	None	17.5	0%	No Data	0	0%	Low	3.5	0%	None	3
327	0%	None	14	0%	None	6.5	100%	High	3.25	0%	None	0.25

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

APPENDIX 6.4

OTHER KEY QUESTIONNAIRE DATA

2023686593

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 4

OTHER KEY QUESTIONNAIRE DATA FOR ALL SUBJECTS

Sub No	Rating of Air Quality	% Exposure in last 6 months occurring at				2 days Pre Test [1]	During Test [2]	No P'ner Smoked	Others Home [3]	Last Smoked
		Home	Work	Travel	Leisure					
1	Good	0%	20%	5%	75%	Y	N	0	N	Never
2	Good	0%	0%	0%	100%	N	N	0	N	Jan-76
3	Good	100%	0%	0%	0%	Y	Y	0	N	Dec-91
4	Good	20%	0%	0%	80%	N	Y	0	Y	02-Oct-92
5	Good	0%	0%	0%	100%	N	N	0	N	Mar-86
7	Very Good	0%	50%	0%	50%	N	Y	0	N	Sep-92
8	Good	95%	0%	0%	5%	Y	Y	0	N	Never
9	Moderate	50%	10%	10%	30%	Y	Y	6	Y	Never
10	Moderate	0%	25%	0%	75%	N	N	0	N	Aug-92
12	Good	0%	20%	0%	80%	N	N	0	N	Never
13	Moderate	0%	0%	0%	100%	N	N	0	N	Never
14	Moderate	0%	100%	0%	0%	N	N	0	N	Never
15	Moderate	0%	0%	10%	90%	N	N	0	N	Jun-76
16	Good	10%	40%	10%	40%	Y	Y	6	N	Never
17	Good	0%	0%	0%	100%	N	N	0	N	Jan-86
18	Good	0%	10%	0%	90%	Y	N	0	N	Jan-89
19	Good	0%	100%	0%	0%	N	N	0	N	Apr-92

[1]&[2] ... Responses to questions if anybody smoked in the home either in the 2 days prior to [1], or during [2], the test period.
[3] ... Response to question "Does any other member (excluding spouse/partner) of your household smoke?"

2023686594

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 4 (continued)

OTHER KEY QUESTIONNAIRE DATA FOR ALL SUBJECTS

Sub No	Rating of Air Quality	% Exposure in last 6 months occurring at Home	Work	Travel	Leisure	2 days Pre Test [1]	During Test [2]	No P'ner Smoked	Others Home [3]	Last Smoked
20	Very Good	67%	0%	0%	33%	N	Y	0	N	Jan-74
22	Good	25%	0%	0%	75%	N	Y	0	N	Jan-86
23	Very Good	0%	80%	10%	10%	N	N	0	N	Never
24	Moderate	35%	40%	10%	15%	Y	Y	2	N	Jan-85
25	Good	100%	0%	0%	0%	Y	Y	10	N	Never
26	Good	0%	0%	10%	90%	N	N	0	N	Never
27	Very Good	0%	0%	0%	100%	N	N	0	N	Never
28	Good	0%	10%	0%	90%	N	N	0	N	Jan-89
29	Good	5%	0%	0%	95%	N	Y	0	N	Never
30	Very Good	60%	0%	0%	40%	Y	Y	0	Y	Never
31	Good	0%	75%	0%	25%	N	N	0	N	Never
32	Moderate	0%	0%	0%	100%	N	N	0	N	Never
33	Poor	100%	0%	0%	0%	Y	Y	5	Y	Jan-80
35	Good	0%	0%	3%	97%	N	N	0	N	Jan-61
36	Good	5%	85%	0%	10%	N	N	0	Y	Never
37	Good	0%	50%	50%	0%	N	N	0	N	Never
39	Very Good	30%	5%	5%	60%	Y	Y	4	N	Never

[1]&[2] ... Responses to questions if anybody smoked in the home either in the 2 days prior to [1], or during [2], the test period.
[3] ... Response to question "Does any other member (excluding spouse/partner) of your household smoke?"

HWK Study no 12/64

2023686595

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 4 (continued)

OTHER KEY QUESTIONNAIRE DATA FOR ALL SUBJECTS

Sub No	Rating of Air Quality	% Exposure in last 6 months occurring at Home	Work	Travel	Leisure	2 days Pre Test [1]	During Test [2]	No P'ner Smoked	Others Home [3]	Last Smoked
40	Very Good	0%	0%	0%	100%	N	N	0	N	Never
41	Good	0%	70%	0%	30%	Y	N	0	N	Jul-91
42	Good	0%	0%	0%	100%	N	N	0	N	Jan-82
43	Good	0%	0%	0%	100%	N	N	0	N	Never
45	Good	0%	10%	15%	75%	Y	N	0	N	May-92
46	Moderate	0%	80%	0%	20%	N	N	0	N	Jan-90
47	Moderate	10%	0%	0%	90%	N	N	0	Y	Sep-92
48	Good	0%	0%	0%	100%	N	N	0	N	Jan-62
49	Good	0%	25%	0%	75%	N	N	0	N	Never
51	Very Good	0%	80%	0%	20%	N	N	0	N	Never
52	Very Good	10%	0%	0%	90%	Y	Y	2	N	Jan-80
53	Moderate	0%	10%	50%	40%	N	N	0	N	Never
54	Good	30%	0%	30%	40%	N	N	0	N	11-Oct-92
55	Good	0%	0%	50%	50%	N	N	0	N	Never
57	Good	10%	5%	0%	85%	Y	Y	0	Y	Never
58	Poor	0%	0%	100%	0%	N	N	0	N	Never
59	Good	0%	90%	0%	10%	N	N	0	N	Jan-79

[1]&[2] ... Responses to questions if anybody smoked in the home either in the 2 days prior to [1], or during [2], the test period.
[3] ... Response to question "Does any other member (excluding spouse/partner) of your household smoke?"

HUK Study no 12/64

2023686596

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 4 (continued)

OTHER KEY QUESTIONNAIRE DATA FOR ALL SUBJECTS

Sub No	Rating of Air Quality	% Exposure in last 6 months occurring at Home	Work	Travel	Leisure	2 days Pre Test [1]	During Test [2]	No P'ner Smoked	Others Home [3]	Last Smoked
60	Good	0%	0%	0%	100%	N	N	0	N	Jan-75
61	Very Good	0%	90%	0%	10%	Y	N	0	N	Jan-75
62	Good	0%	0%	0%	100%	N	N	0	N	Jan-81
63	Good	100%	0%	0%	0%	N	Y	0	N	Jan-89
64	Poor	0%	0%	0%	100%	N	N	0	N	Jan-89
66	Moderate	0%	0%	0%	100%	Y	N	0	N	Jan-75
67	Good	100%	0%	0%	0%	Y	Y	10	N	Never
68	Poor	5%	95%	0%	0%	Y	N	0	N	Never
70	Moderate	90%	0%	0%	10%	Y	Y	3	N	Jan-84
71	Good	0%	0%	0%	100%	N	N	0	N	Never
73	Moderate	5%	5%	10%	80%	N	N	0	N	Jan-90
74	Good	0%	100%	0%	0%	N	N	0	N	Jan-84
77	Very Good	0%	0%	0%	100%	N	N	0	N	Never
78	Very Good	10%	0%	0%	90%	Y	Y	0	Y	Never
79	Moderate	0%	0%	0%	100%	N	N	0	N	Never
80	Good	0%	0%	0%	100%	N	N	0	N	Never
82	Good	5%	50%	0%	45%	N	N	0	N	Never

[1]&[2] ... Responses to questions if anybody smoked in the home either in the 2 days prior to [1], or during [2], the test period.
[3] ... Response to question "Does any other member (excluding spouse/partner) of your household smoke?"

2023686597

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 4 (continued)

OTHER KEY QUESTIONNAIRE DATA FOR ALL SUBJECTS

Sub No	Rating of Air Quality	% Exposure in last 6 months occurring at Home	Work	Travel	Leisure	2 days Pre Test [1]	During Test [2]	No P'ner Smoked	Others Home [3]	Last Smoked
83	Good	0%	0%	0%	100%	N	N	0	N	Jan-90
84	Good	25%	0%	0%	75%	Y	Y	0	Y	Jan-82
85	Good	0%	50%	0%	50%	N	N	0	N	Jan-72
86	Moderate	0%	0%	0%	100%	N	N	0	N	Jan-76
87	Moderate	0%	50%	0%	50%	N	Y	0	N	Mar-92
88	Good	80%	3%	17%	0%	Y	Y	10	N	Never
89	Poor	20%	0%	0%	80%	N	Y	0	N	01-Oct-92
90	Very Good	90%	0%	0%	10%	Y	Y	8	Y	Never
91	Moderate	0%	80%	0%	20%	N	N	0	N	Jan-90
92	Very Good	0%	100%	0%	0%	N	N	0	N	Jan-63
93	Good	0%	10%	0%	90%	N	N	0	N	Never
94	Moderate	0%	100%	0%	0%	N	N	0	N	Jan-80
95	Good	0%	10%	0%	90%	Y	N	0	N	Jun-92
96	Good	5%	0%	0%	95%	Y	Y	0	Y	Jan-87
97	Good	0%	30%	0%	70%	N	N	0	N	Jan-84
100	Moderate	10%	0%	0%	90%	N	Y	0	N	Never
101	Moderate	25%	25%	0%	50%	Y	N	0	N	Jan-80

[1]&[2] ... Responses to questions if anybody smoked in the home either in the 2 days prior to [1], or during [2], the test period.
[3] ... Response to question "Does any other member (excluding spouse/partner) of your household smoke?"

2023686598

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 4 (continued)

OTHER KEY QUESTIONNAIRE DATA FOR ALL SUBJECTS

Sub No	Rating of Air Quality	% Exposure in last 6 months occurring at				2 days Pre Test [1]	During Test [2]	No P'ner Smoked	Others Home [3]	Last Smoked
		Home	Work	Travel	Leisure					
102	Good	0%	0%	0%	100%	N	N	0	N	Never
103	Very Good	0%	0%	0%	100%	N	N	0	N	Jan-76
104	Good	0%	10%	0%	90%	N	N	0	N	Jan-77
105	Good	45%	0%	10%	45%	Y	Y	10	N	Never
106	Very Good	20%	50%	10%	20%	Y	N	0	N	Never
107	Good	1%	0%	0%	99%	N	N	0	N	Jan-86
108	Moderate	0%	45%	10%	45%	N	N	0	N	Never
109	Good	0%	10%	0%	90%	N	N	0	N	Never
112	Moderate	0%	25%	0%	75%	N	N	0	N	Apr-92
113	Good	0%	90%	0%	10%	N	N	0	N	Never
114	Very Good	0%	20%	0%	80%	N	N	0	N	Never
115	Very Good	0%	0%	0%	100%	Y	N	0	N	Never
118	Moderate	30%	60%	0%	10%	Y	Y	4	N	Never
119	Good	2%	2%	6%	90%	N	N	0	N	Jan-78
120	Good	30%	0%	0%	70%	Y	Y	0	Y	Aug-92
121	Moderate	60%	0%	10%	30%	Y	Y	4	Y	Never
122	Moderate	20%	0%	0%	80%	N	Y	0	N	Jan-52

[1]&[2] ... Responses to questions if anybody smoked in the home either in the 2 days prior to [1], or during [2], the test period.
[3] ... Response to question "Does any other member (excluding spouse/partner) of your household smoke?"

HUK Study no 12/64

2023686599

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 4 (continued)

OTHER KEY QUESTIONNAIRE DATA FOR ALL SUBJECTS

Sub No	Rating of Air Quality	% Exposure in last 6 months occurring at Home	Work	Travel	Leisure	2 days Pre Test [1]	During Test [2]	No P'ner Smoked	Others Home [3]	Last Smoked
123	Moderate	0%	5%	45%	50%	N	N	0	N	Jan-84
135	Very Good	0%	0%	0%	100%	N	N	0	N	Never
137	Very Good	0%	80%	0%	20%	N	N	0	N	Never
138	Very Good	0%	70%	0%	30%	N	N	0	N	Never
139	Very Good	0%	10%	0%	90%	N	N	0	N	Never
145	Good	0%	0%	5%	95%	N	N	0	N	Never
146	Poor	0%	100%	0%	0%	N	N	0	N	Never
147	Poor	90%	0%	0%	10%	N	N	0	N	Jan-80
148	Good	50%	25%	10%	15%	Y	Y	2	N	Never
150	Good	100%	0%	0%	0%	Y	Y	0	N	Never
151	Moderate	0%	75%	0%	25%	N	N	0	N	Nov-91
152	Good	20%	20%	0%	60%	Y	Y	0	Y	Never
153	Very Good	10%	45%	0%	45%	N	N	0	N	Jan-82
154	Very Good	0%	15%	0%	85%	N	N	0	N	Never
155	Good	30%	10%	0%	60%	N	N	0	N	Jan-85
156	Poor	10%	0%	0%	90%	N	N	0	N	Never
157	Good	0%	0%	0%	100%	N	N	0	N	Never

[1]&[2] ... Responses to questions if anybody smoked in the home either in the 2 days prior to [1], or during [2], the test period.
[3] ... Response to question "Does any other member (excluding spouse/partner) of your household smoke?"

2023686600

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 4 (continued)

OTHER KEY QUESTIONNAIRE DATA FOR ALL SUBJECTS

Sub No	Rating of Air Quality	% Exposure in last 6 months occurring at Home	Work	Travel	Leisure	2 days Pre Test [1]	During Test [2]	No P'ner Smoked	Others Home [3]	Last Smoked
159	Poor	10%	0%	40%	50%	N	N	0	Y	Never
166	Very Good	0%	95%	0%	5%	N	N	0	N	Never
168	Good	20%	30%	10%	40%	Y	Y	6	N	Jan-82
169	Good	30%	0%	10%	60%	Y	Y	3	N	Never
170	Good	10%	80%	0%	10%	Y	N	0	N	Jan-72
171	Good	0%	10%	20%	70%	Y	Y	0	N	Never
172	Moderate	40%	10%	0%	50%	Y	Y	0	Y	06-Nov-92
173	Good	0%	60%	0%	40%	N	N	0	N	Never
174	Good	10%	10%	0%	80%	N	N	0	N	Jan-86
175	Good	0%	20%	0%	80%	N	N	0	N	25-Oct-92
176	Good	0%	10%	0%	90%	N	N	0	N	Never
177	Good	15%	5%	0%	80%	Y	N	0	N	Never
178	Good	0%	0%	50%	50%	N	N	0	N	Jan-50
179	Moderate	0%	80%	0%	20%	N	N	0	N	Jan-86
180	Very Good	0%	0%	20%	80%	N	N	0	N	Jan-88
181	Moderate	0%	80%	20%	0%	N	N	0	N	Never
182	Good	100%	0%	0%	0%	Y	Y	15	N	Jan-83

[1]&[2] ... Responses to questions if anybody smoked in the home either in the 2 days prior to [1], or during [2], the test period.
[3] ... Response to question "Does any other member (excluding spouse/partner) of your household smoke?"

2023686601

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 4 (continued)

OTHER KEY QUESTIONNAIRE DATA FOR ALL SUBJECTS

Sub No	Rating of Air Quality	% Exposure in last 6 months occurring at Home	Work	Travel	Leisure	2 days Pre Test [1]	During Test [2]	No P'ner Smoked	Others Home [3]	Last Smoked
183	Good	0%	30%	5%	70%	N	N	0	N	Jan-78
184	Good	0%	40%	0%	60%	N	N	0	N	Jan-83
185	Very Good	0%	98%	0%	2%	N	N	0	N	Never
186	Good	0%	100%	0%	0%	N	N	0	N	Nov-86
187	Good	0%	70%	0%	30%	N	N	0	N	Never
188	Moderate	30%	0%	10%	60%	N	N	0	N	Jan-73
189	Good	0%	0%	0%	100%	N	N	0	N	Jan-75
190	Moderate	0%	0%	0%	100%	N	N	0	Y	Jan-86
191	Moderate	0%	60%	0%	40%	N	N	0	N	Jan-91
192	Good	1%	80%	0%	19%	N	Y	0	N	Jun-92
193	Very Good	0%	0%	90%	10%	N	Y	0	N	Jan-80
194	Good	80%	0%	5%	15%	Y	Y	2	Y	Jan-80
195	Good	0%	0%	0%	100%	N	N	0	N	05-Nov-92
196	Good	10%	80%	0%	10%	N	N	0	N	Never
197	Good	70%	10%	5%	15%	Y	Y	2	N	Never
198	Good	0%	0%	0%	100%	N	N	0	N	Never
199	Very Good	0%	10%	0%	90%	N	N	0	N	Never

[1]&[2] ... Responses to questions if anybody smoked in the home either in the 2 days prior to [1], or during [2], the test period.
[3] ... Response to question "Does any other member (excluding spouse/partner) of your household smoke?"

HUK Study no 12/64

2023686602

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 4 (continued)

OTHER KEY QUESTIONNAIRE DATA FOR ALL SUBJECTS

Sub No	Rating of Air Quality	% Exposure in last 6 months occurring at Home	Work	Travel	Leisure	2 days Pre Test [1]	During Test [2]	No P'ner Smoked	Others Home [3]	Last Smoked
200	Very Good	0%	10%	0%	90%	N	Y	0	N	Jan-78
201	Good	0%	25%	0%	75%	N	N	0	N	Jan-82
202	Poor	0%	85%	5%	10%	Y	N	0	N	Never
203	Good	10%	30%	20%	40%	N	N	0	N	Jan-88
204	Very Good	0%	33%	33%	34%	N	N	0	N	Jan-73
205	Good	5%	5%	0%	90%	Y	N	0	Y	Jan-79
206	Good	0%	70%	20%	10%	Y	Y	0	N	Never
207	Moderate	20%	0%	5%	75%	Y	Y	0	Y	01-Nov-92
208	Good	0%	10%	0%	90%	N	N	0	N	Oct-90
209	Moderate	0%	0%	0%	100%	N	N	0	N	Never
210	Very Good	0%	0%	0%	100%	N	N	0	N	Never
214	Poor	0%	25%	0%	75%	N	N	0	N	Jan-82
215	Poor	60%	0%	10%	30%	Y	Y	8	Y	01-Nov-92
216	Very Poor	5%	80%	5%	10%	N	N	0	N	Jan-86
219	Moderate	0%	40%	10%	50%	N	N	0	N	Jan-86
220	Good	0%	0%	0%	100%	N	N	0	N	Never
221	Very Good	0%	0%	0%	100%	Y	N	0	N	Never

[1]&[2] ... Responses to questions if anybody smoked in the home either in the 2 days prior to [1], or during [2], the test period.
[3] ... Response to question "Does any other member (excluding spouse/partner) of your household smoke?"

2023686603

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 4 (continued)

OTHER KEY QUESTIONNAIRE DATA FOR ALL SUBJECTS

Sub No	Rating of Air Quality	% Exposure in last 6 months occurring at				2 days Pre Test [1]	During Test [2]	No P'ner Smoked	Others Home [3]	Last Smoked
		Home	Work	Travel	Leisure					
222	Good	0%	35%	0%	65%	N	N	0	N	Never
223	Moderate	50%	50%	0%	0%	Y	Y	0	Y	Never
224	Very Good	0%	10%	0%	90%	N	N	0	N	Jan-72
225	Very Good	0%	0%	0%	100%	N	N	0	N	Never
226	Good	5%	35%	25%	35%	N	N	0	Y	19-Oct-92
227	Good	0%	10%	10%	80%	N	N	0	N	12-Nov-92
228	Good	0%	60%	10%	30%	Y	N	0	N	Never
229	Very Good	0%	70%	0%	30%	N	N	0	N	Jan-70
230	Moderate	0%	0%	0%	100%	N	N	0	N	Never
232	Moderate	0%	70%	0%	30%	N	N	0	N	Jan-84
233	Moderate	20%	55%	5%	20%	Y	Y	0	Y	Never
234	Good	20%	70%	10%	0%	Y	Y	0	N	Never
235	Moderate	0%	0%	100%	0%	N	N	0	N	Never
236	Moderate	0%	0%	0%	100%	N	N	0	N	Never
237	Good	50%	0%	0%	50%	Y	Y	1	N	Never
238	Good	0%	20%	0%	80%	N	N	0	N	Nov-88
239	Moderate	25%	70%	0%	5%	Y	Y	0	Y	Nov-88

[1]&[2] ... Responses to questions if anybody smoked in the home either in the 2 days prior to [1], or during [2], the test period.
[3] ... Response to question "Does any other member (excluding spouse/partner) of your household smoke?"

2023686604

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 4 (continued)

OTHER KEY QUESTIONNAIRE DATA FOR ALL SUBJECTS

Sub No	Rating of Air Quality	% Exposure in last 6 months occurring at Home	Work	Travel	Leisure	2 days Pre Test [1]	During Test [2]	No P'ner Smoked	Others Home [3]	Last Smoked
240	Very Poor	5%	0%	0%	95%	Y	N	0	N	Jan-82
241	Moderate	45%	0%	5%	50%	Y	Y	0	Y	Never
242	Moderate	0%	0%	0%	100%	N	N	0	N	Never
243	Poor	60%	0%	5%	35%	Y	Y	6	N	Jan-80
244	Good	0%	75%	0%	25%	N	N	0	N	Never
245	Moderate	0%	50%	0%	50%	N	N	0	N	Never
246	Good	0%	70%	0%	30%	N	N	0	N	Never
247	Good	0%	0%	0%	100%	N	N	0	N	Never
248	Good	0%	10%	0%	90%	N	N	0	N	Nov-80
249	Good	0%	0%	0%	100%	N	N	0	N	Nov-77
251	Moderate	0%	75%	0%	25%	N	N	0	N	Never
255	Poor	30%	0%	20%	50%	Y	Y	0	N	Never
256	Moderate	5%	0%	0%	95%	N	N	0	N	Jan-52
257	Moderate	0%	75%	0%	25%	N	N	0	N	Never
260	Good	0%	0%	25%	75%	N	N	0	N	Jan-86
262	Very Good	33%	33%	0%	34%	Y	N	0	N	23-Nov-92
263	Good	50%	35%	5%	10%	N	Y	0	Y	Jan-90

[1]&[2] ... Responses to questions if anybody smoked in the home either in the 2 days prior to [1], or during [2], the test period.
[3] ... Response to question "Does any other member (excluding spouse/partner) of your household smoke?"

2023686605

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 4 (continued)

OTHER KEY QUESTIONNAIRE DATA FOR ALL SUBJECTS

Sub No	Rating of Air Quality	% Exposure in last 6 months occurring at Home	Work	Travel	Leisure	2 days Pre Test [1]	During Test [2]	No P'ner Smoked	Others Home [3]	Last Smoked
264	Good	0%	80%	0%	20%	N	N	0	N	Feb-90
265	Good	0%	0%	60%	40%	N	N	0	N	Jan-52
266	Good	0%	0%	0%	100%	N	N	0	N	Never
267	Good	0%	0%	0%	0%	N	N	0	N	Never
268	Moderate	0%	0%	0%	100%	N	N	0	N	Never
269	Good	0%	10%	10%	80%	N	N	0	N	Nov-86
271	Good	0%	0%	0%	100%	N	N	0	N	Never
272	Good	0%	0%	0%	100%	N	N	0	N	Never
273	Very Good	0%	75%	0%	25%	N	N	0	N	Jan-89
274	Good	0%	75%	0%	25%	N	N	0	N	Never
275	Very Good	50%	0%	0%	50%	Y	Y	10	N	Jan-88
276	Very Good	0%	30%	0%	70%	N	N	0	N	Jan-75
277	Moderate	0%	90%	10%	0%	Y	N	2	Y	Never
279	Good	50%	50%	0%	0%	Y	Y	10	N	Never
280	Good	0%	0%	0%	100%	N	N	0	N	Never
281	Good	0%	50%	0%	50%	N	N	0	N	Jan-76
282	Moderate	35%	60%	5%	0%	Y	Y	5	Y	Jan-77

[1]&[2] ... Responses to questions if anybody smoked in the home either in the 2 days prior to [1], or during [2], the test period.
[3] ... Response to question "Does any other member (excluding spouse/partner) of your household smoke?"

HUK Study no 12/64

2023686606

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 4 (continued)

OTHER KEY QUESTIONNAIRE DATA FOR ALL SUBJECTS

Sub No	Rating of Air Quality	% Exposure in last 6 months occurring at Home	Work	Travel	Leisure	2 days Pre Test [1]	During Test [2]	No P'ner Smoked	Others Home [3]	Last Smoked
283	Moderate	0%	10%	0%	90%	N	N	0	N	Jan-82
284	Good	0%	0%	5%	95%	N	N	0	N	Jan-82
285	Good	0%	0%	75%	25%	N	N	0	N	Jan-86
286	Moderate	0%	25%	0%	75%	N	N	0	N	Jan-72
287	Moderate	0%	100%	0%	0%	N	N	0	N	Jan-49
288	Moderate	0%	0%	5%	95%	N	N	0	N	Never
289	Moderate	10%	0%	10%	80%	Y	N	0	N	Never
290	Good	80%	10%	0%	10%	Y	Y	0	N	Jan-64
292	Moderate	0%	95%	0%	5%	Y	N	0	N	Jan-82
293	Moderate	0%	20%	0%	80%	N	N	0	N	Never
295	Moderate	45%	0%	10%	45%	Y	Y	6	Y	Never
296	Good	0%	40%	0%	60%	N	N	0	N	Apr-92
297	Good	0%	50%	0%	50%	N	N	0	N	Jan-60
298	Moderate	0%	0%	0%	100%	N	N	0	N	Never
299	Moderate	0%	0%	100%	0%	N	N	0	N	Never
302	Very Good	65%	0%	5%	30%	Y	Y	4	N	Never
303	Good	0%	0%	0%	100%	N	N	0	N	Never

[1]&[2] ... Responses to questions if anybody smoked in the home either in the 2 days prior to [1], or during [2], the test period.
[3] ... Response to question "Does any other member (excluding spouse/partner) of your household smoke?"

HUK Study no 12/64

2023686607

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 4 (continued)

OTHER KEY QUESTIONNAIRE DATA FOR ALL SUBJECTS

Sub No	Rating of Air Quality	% Exposure in last 6 months occurring at Home	Work	Travel	Leisure	2 days Pre Test [1]	During Test [2]	No P'ner Smoked	Others Home [3]	Last Smoked
304	Good	5%	0%	0%	95%	N	N	0	N	Jan-79
305	Good	0%	80%	0%	20%	N	N	0	N	Never
311	Moderate	30%	50%	0%	20%	Y	Y	0	Y	Never
312	Good	0%	80%	0%	20%	N	N	0	N	Never
313	Good	0%	0%	0%	100%	Y	Y	0	Y	Jan-72
314	Good	0%	20%	0%	80%	N	N	0	N	Jan-87
315	Good	50%	0%	0%	50%	Y	Y	1	N	Never
316	Moderate	0%	20%	0%	80%	N	N	0	Y	Jan-82
317	Good	100%	0%	0%	0%	Y	Y	1	Y	Never
318	Moderate	70%	10%	0%	20%	Y	Y	5	N	Never
319	Poor	40%	0%	20%	40%	Y	Y	2	N	Dec-91
320	Good	5%	90%	0%	5%	Y	Y	0	N	Never
321	Moderate	0%	0%	0%	100%	N	N	0	N	Never
322	Moderate	75%	0%	0%	25%	Y	Y	0	Y	Never
323	Moderate	0%	0%	5%	95%	N	N	0	N	Mar-83
324	Moderate	0%	0%	0%	100%	N	N	0	N	Never
327	Moderate	5%	10%	10%	75%	N	N	0	N	07-Dec-92

[1]&[2] ... Responses to questions if anybody smoked in the home either in the 2 days prior to [1], or during [2], the test period.
[3] ... Response to question "Does any other member (excluding spouse/partner) of your household smoke?"

2023686608

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

APPENDIX 6.5

KEY ANALYTICAL STATISTICS FOR ALL SUBJECTS BY AGE AND SEX

2023686609

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 5

KEY ANALYTICAL STATISTICS FOR ALL SUBJECTS BY AGE AND SEX

	Age Range....	All Ages			21-29		30-39		40-49		50-61	
	Sex.....	Both	M	F	M	F	M	F	M	F	M	F
Total No of Subjects		255	108	147	54	57	26	37	16	20	12	33
PAS ($\mu g/m^3$)	No of Results	255	108	147	54	57	26	37	16	20	12	33
	mean	179	169	187	163	171	177	208	181	205	158	183
	median	142	136	151	129	150	126	190	152	144	155	131
	minimum	20	20	30	45	35	48	52	20	45	29	30
	maximum	1219	1219	847	995	420	1219	539	524	847	286	549
SPM ($\mu g/m^3$)	No of Results	255	108	147	54	57	26	37	16	20	12	33
	mean	12	15	11	17	15	15	10	9	9	13	5
	median	2	4	2	6	2	2	2	2	2	7	2
	minimum	2	2	2	2	2	2	2	2	2	2	2
	maximum	159	159	153	97	153	159	88	51	78	50	87

HUK Study no 12/64

2023686610

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

TABLE 5 (continued)

KEY ANALYTICAL STATISTICS FOR ALL SUBJECTS BY AGE AND SEX

	Age Range....	All Ages			21-29		30-39		40-49		50-61	
	Sex.....	Both	M	F	M	F	M	F	M	F	M	F
Nic ($\mu g/m^3$)	No of Results	249	105	144	52	57	24	35	16	19	12	33
	mean	1.7	2.2	1.4	2.6	1.5	2.0	1.3	1.6	1.6	1.9	1.2
	median	0.50	0.87	0.34	1.62	0.47	0.40	0.23	0.33	0.31	0.69	0.31
	minimum	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05
	maximum	26	26	19	13	15	26	6	11	19	9	18
Pre Cot (ng/mL)	No of Results	254	107	147	54	57	25	37	16	20	12	33
	mean	1.4	1.9	1.0	2.3	1.1	2.0	1.4	0.9	0.7	1.0	0.7
	median	0.7	1.0	0.6	1.4	0.7	0.9	0.3	0.5	0.7	0.4	0.3
	minimum	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
	maximum	14	14	13	14	8.2	13	13	3.4	2.6	4.4	4.2
Post Cot (ng/mL)	No of Results	248	106	142	53	54	25	35	16	20	12	33
	mean	1.4	2.0	1.0	2.3	1.2	2.4	0.9	1.4	0.7	0.8	0.9
	median	0.6	0.7	0.25	1.3	0.7	0.8	0.25	0.25	0.25	0.4	0.25
	minimum	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
	maximum	12	12	8.1	12	7.5	12	7.0	7.8	2.4	2.8	8.1

2023686611

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

APPENDIX 6.6

WEATHER CONDITIONS

(THE LEEDS MET OFFICE)

2023686612

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

WEEKLY WEATHER SUMMARY

The Met. Office
Leeds Weather Centre
Oak House, Park Lane, Leeds LS3 1EL
Telephone Leeds (0532) 415990 or 457753
Telex 557396 / WEALDS G

HAZLETON UK
for the attention of Mr. K. Phillips

FOR LEEDS & HARROGATE area

based on Leeds data

WEEK ENDING SATURDAY : 10th October 1992

ALL TIMES G.M.T.	DATE	TEMPERATURES °C			RAINFALL mm		SUN Hr	MEAN WIND			ADDITIONAL COMMENTS differences noted LEEDS-HARROGATE
		NIGHT MIN	DAY MAX	MEAN RH %	09-21	21-09		DIR'N	SPEED Kt	GUST (kt)	
SUNDAY	04/10	8.6	13.7	73	Trace	0.0	3.2	NE	07	24	
MONDAY	05/10	9.8	11.8	68	Trace	0.5	0.0	NNE	07	22	
TUESDAY	06/10	9.0	11.7	69	Trace	Trace	0.0	NNE	08	25	
WEDNESDAY	07/10	9.1	10.5	82	Trace	Trace	0.0	NNW	06	16	
THURSDAY	08/10	8.6	14.2	62	0.0	Trace	5.0	WNW	11	22	
FRIDAY	09/10	8.3	11.9	61	0.0	Trace	4.3	NNE	08	28	
SATURDAY	10/10	7.9	10.2	70	Trace	Trace	0.0	N	06	19	

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* Data not available.

2023686613

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WEEKLY WEATHER SUMMARY

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HAZLETON UK
for the attention of Mr. K. Phillips

FOR LEEDS & HARROGATE area WEEK ENDING SATURDAY : 17th October 1992

based on Leeds data

ALL TIMES G.M.T.	DATE	TEMPERATURES °C			RAINFALL mm		SUN Hr	MEAN WIND			ADDITIONAL COMMENTS differences noted LEEDS-HARROGATE
		NIGHT MIN	DAY MAX	MEAN RH %	09-21	21-09		DIR'N	SPEED Kt	GUST (kt)	
SUNDAY	11/10	7.3	11.4	76	Tr	0.2	0.1	NNE	07	25	
MONDAY	12/10	7.4	11.2	73	Tr	0.0	1.0	NE	06	19	
TUESDAY	13/10	7.8	11.9	73	0.0	Tr	0.0	W	04	16	
WEDNESDAY	14/10	6.8	10.7	74	1.9	Tr	0.0	W	17	35	
THURSDAY	15/10	1.8	9.4	58	Tr	0.0	6.7	NW	14	33	
FRIDAY	16/10	2.4	8.9	61	Tr	0.0	5.0	NW	09	22	
SATURDAY	17/10	2.0	10.3	55	0.0	1.1	6.6	WNW	10	25	

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* Data not available.

2023686614

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WEEKLY WEATHER SUMMARY

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HAZLETON UK
for the attention of Mr. K. Phillips

FOR LEEDS & HARROGATE area

based on Leeds data

WEEK ENDING SATURDAY : 24 OCTOBER 92

ALL TIMES G.M.T.	DATE	TEMPERATURES °C			RAINFALL mm		SUN Hr	MEAN WIND			ADDITIONAL COMMENTS differences noted LEEDS-HARROGATE
		NIGHT MIN	DAY MAX	MEAN RH %	09-21	21-09		DIR'N	SPEED Kt	GUST (kt)	
SUNDAY	18/10	4.9	10 2	63	0.0	0 0	7.5	W	11	27	
MONDAY	19/10	-0.9	10.1	69	0.0	0.0	6.9	NW	05	15	
TUESDAY	20/10	0 3	10.5	61	0.0	0 0	6.3	NNE	07	24	
WEDNESDAY	21/10	1.3	10.1	71	TR	TR	4.3	W	10	22	
THURSDAY	22/10	5.5	9.2	79	TR	TR	0..0	W	05	18	
FRIDAY	23/10	5.5	8 8	74	0.7	TR	2.9	W	13	34	
SATURDAY	24/10	3.4	8 4	80	1.7	9 7	4.5	W	09	27	

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* Data not available.

2023686615

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WEEKLY WEATHER SUMMARY

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HAZLETON UK
for the attention of Mr. K. Phillips

FOR LEEDS & HARROGATE area

based on Leeds data

WEEK ENDING SATURDAY : 31st October 1992

ALL TIMES G.M.T.	DATE	TEMPERATURES °C			RAINFALL mm		SUN Hr	MEAN WIND			ADDITIONAL COMMENTS differences noted LEEDS-HARROGATE
		NIGHT MIN	DAY MAX	MEAN RH %	09-21	21-09		DIRN	SPEED Kt	GUST (kt)	
SUNDAY	25/10	1.9	5.8	94	4.2	0.0	0.0	NE	07	26	Sleet
MONDAY	26/10	1.2	8.1	81	2.6	2.6	0.1	West	05	16	
TUESDAY	27/10	5.6	8.8	88	13.9	6.9	0.9	West	10	40	Sleet
WEDNESDAY	28/10	1.5	8.7	73	Tr	0.0	4.3	WSW	09	25	
THURSDAY	29/10	4.0	10.4	69	0.0	0.0	5.7	WNW	08	22	
FRIDAY	30/10	0.5	10.6	72	0.0	Tr	5.8	WNW	11	15	
SATURDAY	31/10	-0.2	6.5	60	0.0	0.4	7.0	West	07	22	

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* Data not available.

2023686616

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WEEKLY WEATHER SUMMARY

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HAZLETON UK
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FOR LEEDS & HARROGATE area

based on Leeds data

WEEK ENDING SATURDAY : 7th November 1992

ALL TIMES G M.T.	DATE	TEMPERATURES °C			RAINFALL mm		SUN Hr	MEAN WIND			ADDITIONAL COMMENTS differences noted LEEDS-HARROGATE
		NIGHT MIN	DAY MAX	MEAN RH %	09-21	21-09		DIR'N	SPEED Kt	GUST (kt)	
SUNDAY	01/11	7.1	11.4	71	0 2	4.5	4.1	West	16	38	
MONDAY	02/11	6.9	12.1	69	0.8	Tr	3.0	West	26	61	
TUESDAY	03/11	7.1	9.7	74	0.2	3.9	5.0	WSW	12	37	
WEDNESDAY	04/11	7.0	12.5	75	Tr	Tr	2.3	West	12	27	
THURSDAY	05/11	12.3	14.7	65	0.0	0.0	0.1	West	14	38	
FRIDAY	06/11	9.7	18.9	71	0.0	Tr	4.4	West	13	32	
SATURDAY	07/11	10.8	13.4	80	0.0	0.0	0.1	West	11	31	

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* Data not available.

202368617

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WEEKLY WEATHER SUMMARY

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FOR LEEDS & HARROGATE area

based on Leeds data

WEEK ENDING SATURDAY : 14th November 1992

ALL TIMES G.M.T.	DATE	TEMPERATURES °C			RAINFALL mm		SUN Hr	MEAN WIND			ADDITIONAL COMMENTS differences noted LEEDS-HARROGATE
		NIGHT MIN	DAY MAX	MEAN RH %	09-21	21-09		DIR'N	SPEED Kt	GUST (kt)	
SUNDAY	08/11	-0.6	8.0	89	0.0	0.4	0.2	ESE	04	17	
MONDAY	09/11	7.7	11.3	87	8.3	TR	0.0	SE	08	27	
TUESDAY	10/11	4.7	8.8	77	0.6	5.0	4.3	West	11	34	Hail
WEDNESDAY	11/11	3.6	8.6	78	0.3	3.0	2.7	WNW	15	43	
THURSDAY	12/11	3.0	7.6	71	0.1	TR	4.2	West	18	43	Sleet
FRIDAY	13/11	0.8	6.7	82	0.0	0.0	7.3	WNW	09	16	
SATURDAY	14/11	-3.2	4.2	80	1.1	5.9	0.0	East	06	19	

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* Data not available.

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WEEKLY WEATHER SUMMARY

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FOR LEEDS & HARROGATE area

based on Leeds data

WEEK ENDING SATURDAY : 21st November 1992

ALL TIMES G.M.T.	DATE	TEMPERATURES °C			RAINFALL mm		SUN Hr	MEAN WIND			ADDITIONAL COMMENTS differences noted LEEDS-HARROGATE
		NIGHT MIN	DAY MAX	MEAN RH %	09-21	21-09		DIR'N	SPEED Kt	GUST (kt)	
SUNDAY	15/11	3.1	5.6	91	0.7	1.1	0.0	East	08	18	
MONDAY	16/11	3.1	6.7	86	0.5	0.0	0.1	SE	07	31	
TUESDAY	17/11	1.7	6 5	74	0.0	Tr	6.7	WNW	11	25	
WEDNESDAY	18/11	2.5	11 2	79	0.2	1.5	0.0	West	20	54	
THURSDAY	19/11	3.6	8.1	54	1.3	0.0	5 0	West	20	48	Hail
FRIDAY	20/11	3.3	8 9	72	Tr	0.0	5 6	West	21	49	
SATURDAY	21/11	1 3	10.7	92	10.4	0.2	0.0	East	05	23	

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* Data not available.

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WEEKLY WEATHER SUMMARY

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FOR LEEDS & HARROGATE area WEEK ENDING SATURDAY : 28th November 1992

based on Leeds data

ALL TIMES G.M.T.	DATE	TEMPERATURES °C			RAINFALL mm		SUN Hr	MEAN WIND			ADDITIONAL COMMENTS differences noted LEEDS-HARROGATE
		NIGHT MIN	DAY MAX	MEAN RH %	09-21	21-09		DIR'N	SPEED Kt	GUST (kt)	
SUNDAY	22/11	10.2	14.1	96	3.8	Tr	0.0	ESE	04	23	
MONDAY	23/11	12 7	15 0	68	Tr	0.0	2.0	SSW	14	45	
TUESDAY	24/11	4.7	11.6	67	0.2	6.2	4.8	SE	08	25	
WEDNESDAY	25/11	7.6	9.1	78	5 9	Tr	2.1	SW	12	37	
THURSDAY	26/11	5.3	8.0	74	1.1	0.0	4.0	WSW	15	41	Hail
FRIDAY	27/11	3 1	10.2	72	Tr	0.0	0.0	SW	10	30	
SATURDAY	28/11	4.3	7 6	77	0 0	0 0	5.0	West	12	28	

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* Data not available.

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WEEKLY WEATHER SUMMARY

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HAZLETON UK
for the attention of Mr. K. Phillips

FOR LEEDS & HARROGATE area

based on Leeds data

WEEK ENDING SATURDAY : 5th December 1992

ALL TIMES G.M.T.	DATE	TEMPERATURES °C			RAINFALL mm		SUN Hr	MEAN WIND			ADDITIONAL COMMENTS differences noted LEEDS-HARROGATE
		NIGHT MIN	DAY MAX	MEAN RH %	09-21	21-09		DIR'N	SPEED Kt	GUST (kt)	
SUNDAY	29/11	-0 2	9 0	94	Tr	4 6	0.0	ESE	07	18	
MONDAY	30/11	9 0	13.0	94	10.6	2.8	0.0	South	05	22	
TUESDAY	01/12	3.8	11 3	78	2.6	7 6	1.3	SW	14	42	
WEDNESDAY	02/12	8 9	12.8	89	2.9	Tr	0 0	South	13	49	
THURSDAY	03/12	4.5	5,6	77	1 6	0 1	1.8	SW	11	27	
FRIDAY	04/12	1 9	5.4	83	0.5	0.7	2.3	WSW	06	18	
SATURDAY	05/12	2.7	5.6	80	Tr	0.0	2.5	WSW	10	26	

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* Data not available.

2023686621

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WEEKLY WEATHER SUMMARY

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HAZLETON UK
for the attention of Mr. K. Phillips

FOR LEEDS & HARROGATE area

based on Leeds data

WEEK ENDING SATURDAY : 12th December 1992

ALL TIMES G.M.T.	DATE	TEMPERATURES °C			RAINFALL mm		SUN Hr	MEAN WIND			ADDITIONAL COMMENTS differences noted LEEDS-HARROGATE
		NIGHT MIN	DAY MAX	MEAN RH %	09-21	21-09		DIR'N	SPEED Kt	GUST (kt)	
SUNDAY	06/12	1.6	5.6	83	4.6	2.9	0.8	SE	08	24	
MONDAY	07/12	4.9	8.3	89	0.1	TR	0.9	WNW	07	19	
TUESDAY	08/12	5.1	7.9	75	0.0	1.0	2.4	NW	07	18	
WEDNESDAY	09/12	3.7	6.6	94	0.2	0.0	0.3	NNW	05	12	
THURSDAY	10/12	1.6	6.4	85	0.0	TR	0.5	WSW	07	22	
FRIDAY	11/12	6.1	9.9	94	7.1	0.0	0.0	West	08	18	
SATURDAY	12/12	4.2	7.1	76	TR	0.0	1.0	West	09	26	

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* Data not available.

2023686622

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Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

APPENDIX 6.7

OCCUPATIONS OF THE SUBJECTS

2023686623

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

OCCUPATIONS OF THE SUBJECTS

Students
Nurses
Psychiatric nurse
District nurse
Analytical chemists
Laboratory technicians
Laboratory supervisors
Prison officer (male and female)
General labourers
Housewife
Retired males and females
Government officers
Chartered surveyors
Civil servants
Furnishings designer
Receptionist
Secretary
Hair dresser
Joiner
Cabinet maker
Clinical chemist
Cooks
Policeman
Retail proprietor
Shop Manager
Teachers
Cleaners
Professional golfer
Graphic designer
Bakery assistant

Bus driver
Casino manager
Post man
Company director
Butcher
Motor mechanic
Accountants
Tours consultant
Playground assistant
Care assistants
Scientific report drafter
Resettlement officer
Printer
Driver
Machinist
Computer operator
Computer programmer
Builders
Community charge officer
Telecommunications engineer
Gardener
Fitter
Probation Officer
Credit controller
Machine operator
Glazier
Planning consultant
Artificial limb technician
Medical writer
Usherette

2023686624

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

Homecare assistants
Quantity surveyor
Aircraft technician
Scientists
Electrician
Communications controller
Production designer
Solicitor
Musician
Caterer
Swimming pool manager
Book binder
Agricultural advisor
Cytogeneticist
Dentist
Waiters
Potter

2023686625

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

APPENDIX 6.8

AGE AND SEX DISTRIBUTION OF THE SUBJECTS

2023686626

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

HUK Study no 12/64

AGE AND SEX DISTRIBUTION

Age range	Male	Females	Total
21 to 29	54	57	111
30 to 39	26	37	63
40 to 49	16	20	36
50 to 61	12	33	45
Total	108	147	255

2023686627

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000

2023686628

Source: https://www.industrydocuments.ucsf.edu/docs/lslm0000